

103D CONGRESS
1ST SESSION

H. R. 4

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 5, 1993

Mr. WAXMAN (for himself, Mr. UPTON, Mrs. SCHROEDER, Ms. SNOWE, Mrs. COLLINS of Illinois, Ms. DANNER, Ms. ENGLISH, Mrs. JOHNSON of Connecticut, Mrs. KENNELLY, Ms. LAMBERT, Mr. LEHMAN, Mrs. LOWEY of New York, Mrs. LLOYD, Mr. MARKEY, Mrs. MINK, Mrs. MORELLA, Ms. MOLINARI, Ms. NORTON, Mr. RICHARDSON, Ms. PELOSI, Mr. SANDERS, Ms. SCHENK, Mr. SHARP, Ms. SLAUGHTER, Mr. STUDDS, Mr. SYNAR, Mr. TOWNS, Mrs. UNSOELD, Ms. WATERS, Ms. WOOLSEY, and Mr. WYDEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “National Institutes of Health Revitalization Act of
6 1993”.

1 (b) TABLE OF CONTENTS.—The table of contents for
 2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—GENERAL PROVISIONS REGARDING TITLE IV OF
 PUBLIC HEALTH SERVICE ACT

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL
 RESEARCH

Sec. 101. Establishment of certain provisions regarding research conducted or
 supported by National Institutes of Health.

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

Sec. 111. Establishment of authorities.

Sec. 112. Purchase of human fetal tissue; solicitation or acceptance of tissue
 as directed donation for use in transplantation.

Sec. 113. Nullification of moratorium.

Sec. 114. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Sec. 131. Requirement of inclusion in research.

Sec. 132. Peer review.

Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

Sec. 141. Establishment.

Subtitle C—Scientific Integrity

Sec. 151. Establishment of Office of Scientific Integrity.

Sec. 152. Commission on Scientific Integrity.

Sec. 153. Protection of whistleblowers.

Sec. 154. Requirement of regulations regarding protection against financial
 conflicts of interest in certain projects of research.

Sec. 155. Effective dates.

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

Sec. 201. Health promotion research dissemination.

Sec. 202. Programs for increased support regarding certain States and re-
 searchers.

Sec. 203. Children's vaccine initiative.

Sec. 204. Plan for use of animals in research.

Sec. 205. Increased participation of women and disadvantaged individuals in
 fields of biomedical and behavioral research.

- Sec. 206. Requirements regarding surveys of sexual behavior.
- Sec. 207. Discretionary fund of Director of National Institutes of Health.
- Sec. 208. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

- Sec. 301. Appointment and authority of Directors of national research institutes.
- Sec. 302. Program of research on osteoporosis, Paget's disease, and related disorders.
- Sec. 303. Establishment of interagency program for trauma research.

TITLE IV—NATIONAL CANCER INSTITUTE

- Sec. 401. Expansion and intensification of activities regarding breast cancer.
- Sec. 402. Expansion and intensification of activities regarding prostate cancer.
- Sec. 403. Authorization of appropriations.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

- Sec. 501. Education and training.
- Sec. 502. Centers for the study of pediatric cardiovascular diseases.
- Sec. 503. National Center on Sleep Disorders.
- Sec. 504. Authorization of appropriations.

TITLE VI—NATIONAL INSTITUTE ON DIABETES AND DIGESTIVE AND KIDNEY DISEASES

- Sec. 601. Provisions regarding nutritional disorders.

TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

- Sec. 701. Juvenile arthritis.

TITLE VIII—NATIONAL INSTITUTE ON AGING

- Sec. 801. Alzheimer's disease registry.
- Sec. 802. Aging processes regarding women.
- Sec. 803. Authorization of appropriations.
- Sec. 804. Conforming amendment.

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

- Sec. 901. Tropical diseases.
- Sec. 902. Chronic fatigue syndrome.

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Subtitle A—Research Centers With Respect to Contraception and Research Centers With Respect to Infertility

- Sec. 1001. Grants and contracts for research centers.
- Sec. 1002. Loan repayment program for research with respect to contraception and infertility.

Subtitle B—Program Regarding Obstetrics and Gynecology

Sec. 1011. Establishment of program.

Subtitle C—Child Health Research Centers

Sec. 1021. Establishment of centers.

Subtitle D—Study Regarding Adolescent Health.

Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

Sec. 1101. Clinical research on diabetes eye care.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL
DISORDERS AND STROKE

Sec. 1201. Research on multiple sclerosis.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH
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Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

Sec. 1401. Additional authorities.

Sec. 1402. Authorization of appropriations.

Subtitle B—Financial Assistance

Sec. 1411. Establishment of program of grants for development of education technologies.

Subtitle C—National Information Center on Health Services Research and
Health Care Technology

Sec. 1421. Establishment of Center.

Sec. 1422. Conforming provisions.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF
HEALTH

Subtitle A—Division of Research Resources

Sec. 1501. Redesignation of Division as National Center for Research Resources.

Sec. 1502. Biomedical and behavioral research facilities.

Sec. 1503. Construction program for national primate research center.

Subtitle B—National Center for Nursing Research

Sec. 1511. Redesignation of National Center for Nursing Research as National Institute of Nursing Research.

Sec. 1512. Study on adequacy of number of nurses.

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

Sec. 1601. Requirement regarding women and individuals from disadvantaged backgrounds.

Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

Subtitle D—Scholarship and Loan Repayment Programs Regarding Professional Skills Needed by National Institutes of Health

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Date certain for appointment of Board members.

Sec. 1702. Miscellaneous provisions.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Sec. 1801. Revision and extension of various programs.

TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.

Sec. 1902. Malnutrition in the elderly.

Sec. 1903. Research activities on chronic fatigue syndrome.

Sec. 1904. Report on medical uses of biological agents in development of defenses against biological warfare.

Sec. 1905. Personnel study of recruitment, retention and turnover.

Sec. 1906. Procurement.

TITLE XX—MISCELLANEOUS PROVISIONS

Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio Conte, and limitation on number of members.

Sec. 2002. Technical corrections.

Sec. 2003. Biennial report on carcinogens.

Sec. 2004. Master plan for physical infrastructure for research.

Sec. 2005. Transfer of provisions of title xxvii.

Sec. 2006. Certain authorization of appropriations.

TITLE XXI—EFFECTIVE DATES

Sec. 2101. Effective dates.

1 **TITLE I—GENERAL PROVISIONS**
 2 **REGARDING TITLE IV OF PUB-**
 3 **LIC HEALTH SERVICE ACT**
 4 **Subtitle A—Research Freedom**

5 **PART I—REVIEW OF PROPOSALS FOR**
 6 **BIOMEDICAL AND BEHAVIORAL RESEARCH**

7 **SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS RE-**
 8 **GARDING RESEARCH CONDUCTED OR SUP-**
 9 **PORTED BY NATIONAL INSTITUTES OF**
 10 **HEALTH.**

11 Part G of title IV of the Public Health Service Act
 12 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
 13 tion 492 the following new section:

14 “CERTAIN PROVISIONS REGARDING REVIEW AND
 15 APPROVAL OF PROPOSALS FOR RESEARCH

16 “SEC. 492A. (a) REVIEW AS PRECONDITION TO RE-
 17 SEARCH.—

18 “(1) PROTECTION OF HUMAN RESEARCH SUB-
 19 JECTS.—

20 “(A) In the case of any application submit-
 21 ted to the Secretary for financial assistance to
 22 conduct research, the Secretary may not ap-
 23 prove or fund any application that is subject to
 24 review under section 491(a) by an Institutional
 25 Review Board unless the application has under-

1 gone review in accordance with such section and
2 has been recommended for approval by a major-
3 ity of the members of the Board conducting
4 such review.

5 “(B) In the case of research that is subject
6 to review under procedures established by the
7 Secretary for the protection of human subjects
8 in clinical research conducted by the National
9 Institutes of Health, the Secretary may not au-
10 thorize the conduct of the research unless the
11 research has, pursuant to such procedures, been
12 recommended for approval.

13 “(2) PEER REVIEW.—In the case of any appli-
14 cation submitted to the Secretary for financial as-
15 sistance to conduct research, the Secretary may not
16 approve or fund any application that is subject to
17 technical and scientific peer review under section
18 492(a) unless the application has undergone peer re-
19 view in accordance with such section and has been
20 recommended for approval by a majority of the
21 members of the entity conducting such review.

22 “(b) ETHICAL REVIEW OF RESEARCH.—

23 “(1) PROCEDURES REGARDING WITHHOLDING
24 OF FUNDS.—If research has been recommended for
25 approval for purposes of subsection (a), the Sec-

1 retary may not withhold funding for the research on
2 ethical grounds unless—

3 “(A) the Secretary convenes an advisory
4 board in accordance with paragraph (4) to
5 study the ethical implications of the research;
6 and

7 “(B) the majority of the advisory board
8 recommends that, on ethical grounds, the Sec-
9 retary withhold funds for the research.

10 “(2) APPLICABILITY.—The limitation estab-
11 lished in paragraph (1) regarding the authority to
12 withhold funds on ethical grounds shall apply with-
13 out regard to whether the withholding of funds is
14 characterized as a disapproval, a moratorium, a pro-
15 hibition, or other description.

16 “(3) PRELIMINARY MATTERS REGARDING USE
17 OF PROCEDURES.—

18 “(A) If the Secretary makes a determina-
19 tion that an advisory board should be convened
20 for purposes of paragraph (1), the Secretary
21 shall, through a statement published in the
22 Federal Register, announce the intention of the
23 Secretary to convene such a board.

24 “(B) A statement issued under subpara-
25 graph (A) shall include a request that inter-

1 ested individuals submit to the Secretary rec-
2 ommendations specifying the particular individ-
3 uals who should be appointed to the advisory
4 board involved. The Secretary shall consider
5 such recommendations in making appointments
6 to the board.

7 “(C) The Secretary may not make appoint-
8 ments to an advisory board under paragraph
9 (1) until the expiration of the 30-day period be-
10 ginning on the date on which the statement re-
11 quired in subparagraph (A) is made with re-
12 spect to the board.

13 “(4) ETHICS ADVISORY BOARDS.—

14 “(A) Any advisory board convened for pur-
15 poses of paragraph (1) shall be known as an
16 ethics advisory board (hereafter in this para-
17 graph referred to as an ‘ethics board’).

18 “(B)(i) An ethics board shall advise, con-
19 sult with, and make recommendations to the
20 Secretary regarding the ethics of the project of
21 biomedical or behavioral research with respect
22 to which the board has been convened.

23 “(ii) Not later than 180 days after the
24 date on which the statement required in para-
25 graph (3)(A) is made with respect to an ethics

1 board, the board shall submit to the Secretary,
2 and to the Committee on Energy and Com-
3 merce of the House of Representatives and the
4 Committee on Labor and Human Resources of
5 the Senate, a report describing the findings of
6 the board regarding the project of research in-
7 volved and making a recommendation under
8 clause (i) of whether the Secretary should or
9 should not withhold funds for the project. The
10 report shall include the information considered
11 in making the findings.

12 “(C) An ethics board shall be composed of
13 no fewer than 14, and no more than 20, indi-
14 viduals who are not officers or employees of the
15 United States. The Secretary shall make ap-
16 pointments to the board from among individ-
17 uals with special qualifications and competence
18 to provide advice and recommendations regard-
19 ing ethical matters in biomedical and behavioral
20 research. Of the members of the board—

21 “(i) no fewer than 1 shall be an attor-
22 ney;

23 “(ii) no fewer than 1 shall be an
24 ethicist;

1 “(iii) no fewer than 1 shall be a prac-
2 ticing physician;

3 “(iv) no fewer than 1 shall be a theo-
4 logian; and

5 “(v) no fewer than one-third, and no
6 more than one-half, shall be scientists with
7 substantial accomplishments in biomedical
8 or behavioral research.

9 “(D) The term of service as a member of
10 an ethics board shall be for the life of the
11 board. If such a member does not serve the full
12 term of such service, the individual appointed to
13 fill the resulting vacancy shall be appointed for
14 the remainder of the term of the predecessor of
15 the individual.

16 “(E) A member of an ethics board shall be
17 subject to removal from the board by the Sec-
18 retary for neglect of duty or malfeasance or for
19 other good cause shown.

20 “(F) The Secretary shall designate an indi-
21 vidual from among the members of an ethics
22 board to serve as the chair of the board.

23 “(G) In carrying out subparagraph (B)(i)
24 with respect to a project of research, an ethics

1 board shall conduct inquiries and hold public
2 hearings.

3 “(H) With respect to information relevant
4 to the duties described in subparagraph (B)(i),
5 an ethics board shall have access to all such in-
6 formation possessed by the Department of
7 Health and Human Services, or available to the
8 Secretary from other agencies.

9 “(I) Members of an ethics board shall re-
10 ceive compensation for each day engaged in car-
11 rying out the duties of the board, including
12 time engaged in traveling for purposes of such
13 duties. Such compensation may not be provided
14 in an amount in excess of the maximum rate of
15 basic pay payable for GS-18 of the General
16 Schedule.

17 “(J) The Secretary, acting through the Di-
18 rector of the National Institutes of Health,
19 shall provide to each ethics board such staff
20 and other assistance as may be necessary to
21 carry out the duties of the board.

22 “(K) An ethics board shall terminate 30
23 days after the date on which the report required
24 in subparagraph (B)(ii) is submitted to the Sec-

1 retary and the congressional committees speci-
2 fied in such subparagraph.”.

3 **PART II—RESEARCH ON TRANSPLANTATION OF**
4 **FETAL TISSUE**

5 **SEC. 111. ESTABLISHMENT OF AUTHORITIES.**

6 Part G of title IV of the Public Health Service Act
7 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
8 tion 498 the following new section:

9 “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

10 “SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

11 “(1) IN GENERAL.—The Secretary may conduct
12 or support research on the transplantation of human
13 fetal tissue for therapeutic purposes.

14 “(2) SOURCE OF TISSUE.—Human fetal tissue
15 may be used in research carried out under para-
16 graph (1) regardless of whether the tissue is ob-
17 tained pursuant to a spontaneous or induced abor-
18 tion or pursuant to a stillbirth.

19 “(b) INFORMED CONSENT OF DONOR.—

20 “(1) IN GENERAL.—In research carried out
21 under subsection (a), human fetal tissue may be
22 used only if the woman providing the tissue makes
23 a statement, made in writing and signed by the
24 woman, declaring that—

25 “(A) the woman donates the fetal tissue
26 for use in research described in subsection (a);

1 “(B) the donation is made without any re-
2 striction regarding the identity of individuals
3 who may be the recipients of transplantations
4 of the tissue; and

5 “(C) the woman has not been informed of
6 the identity of any such individuals.

7 “(2) ADDITIONAL STATEMENT.—In research
8 carried out under subsection (a), human fetal tissue
9 may be used only if the attending physician with re-
10 spect to obtaining the tissue from the woman in-
11 volved makes a statement, made in writing and
12 signed by the physician, declaring that—

13 “(A) in the case of tissue obtained pursu-
14 ant to an induced abortion—

15 “(i) the consent of the woman for the
16 abortion was obtained prior to requesting
17 or obtaining consent for the tissue to be
18 used in such research; and

19 “(ii) no alteration of the timing,
20 method, or procedures used to terminate
21 the pregnancy was made solely for the pur-
22 poses of obtaining the tissue;

23 “(B) the tissue has been donated by the
24 woman in accordance with paragraph (1); and

1 “(C) full disclosure has been provided to
2 the woman with regard to—

3 “(i) such physician’s interest, if any,
4 in the research to be conducted with the
5 tissue; and

6 “(ii) any known medical risks to the
7 woman or risks to her privacy that might
8 be associated with the donation of the tis-
9 sue and that are in addition to risks of
10 such type that are associated with the
11 woman’s medical care.

12 “(c) INFORMED CONSENT OF RESEARCHER AND
13 DONEE.—In research carried out under subsection (a),
14 human fetal tissue may be used only if the individual with
15 the principal responsibility for conducting the research in-
16 volved makes a statement, made in writing and signed by
17 the individual, declaring that the individual—

18 “(1) is aware that—

19 “(A) the tissue is human fetal tissue;

20 “(B) the tissue may have been obtained
21 pursuant to a spontaneous or induced abortion
22 or subsequent to a stillbirth; and

23 “(C) the tissue was donated for research
24 purposes;

1 “(2) has provided such information to other in-
2 dividuals with responsibilities regarding the research;

3 “(3) will require, prior to obtaining the consent
4 of an individual to be a recipient of a transplan-
5 tation of the tissue, written acknowledgment of re-
6 ceipt of such information by such recipient; and

7 “(4) has had no part in any decisions as to the
8 timing, method, or procedures used to terminate the
9 pregnancy made solely for the purposes of the re-
10 search.

11 “(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

12 “(1) IN GENERAL.—In research carried out
13 under subsection (a), human fetal tissue may be
14 used only if the head of the agency or other entity
15 conducting the research involved certifies to the Sec-
16 retary that the statements required under sub-
17 sections (a)(3), (b)(2), and (c) will be available for
18 audit by the Secretary.

19 “(2) CONFIDENTIALITY OF AUDIT.—Any audit
20 conducted by the Secretary pursuant to paragraph
21 (1) shall be conducted in a confidential manner to
22 protect the privacy rights of the individuals and enti-
23 ties involved in such research, including such indi-
24 viduals and entities involved in the donation, trans-
25 fer, receipt, or transplantation of human fetal tissue.

1 With respect to any material or information obtained
2 pursuant to such audit, the Secretary shall—

3 “(A) use such material or information only
4 for the purposes of verifying compliance with
5 the requirements of this section;

6 “(B) not disclose or publish such material
7 or information, except where required by Fed-
8 eral law, in which case such material or infor-
9 mation shall be coded in a manner such that
10 the identities of such individuals and entities
11 are protected; and

12 “(C) not maintain such material or infor-
13 mation after completion of such audit, except
14 where necessary for the purposes of such audit.

15 “(e) APPLICABILITY OF STATE AND LOCAL LAW.—

16 “(1) RESEARCH CONDUCTED BY RECIPIENTS
17 OF ASSISTANCE.—The Secretary may not provide
18 support for research under subsection (a) to conduct
19 the research in accordance with applicable State and
20 local law.

21 “(2) RESEARCH CONDUCTED BY SECRETARY.—
22 The Secretary may conduct research under sub-
23 section (a) only in accordance with applicable State
24 and local law.

1 “(f) DEFINITION.—For purposes of this section, the
 2 term ‘human fetal tissue’ means tissue or cells obtained
 3 from a dead human embryo or fetus after a spontaneous
 4 or induced abortion, or after a stillbirth.”.

5 **SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-**
 6 **TION OR ACCEPTANCE OF TISSUE AS DI-**
 7 **RECTED DONATION FOR USE IN TRANSPLAN-**
 8 **TATION.**

9 Part G of title IV of the Public Health Service Act,
 10 as amended by section 111 of this Act, is amended by in-
 11 serting after section 498A the following new section:

12 “PROHIBITIONS REGARDING HUMAN FETAL TISSUE

13 “SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be
 14 unlawful for any person to knowingly acquire, receive, or
 15 otherwise transfer any human fetal tissue for valuable con-
 16 sideration if the transfer affects interstate commerce.

17 “(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS
 18 DIRECTED DONATION FOR USE IN TRANSPLANTATION.—
 19 It shall be unlawful for any person to solicit or knowingly
 20 acquire, receive, or accept a donation of human fetal tissue
 21 for the purpose of transplantation of such tissue into an-
 22 other person if the donation affects interstate commerce,
 23 the tissue will be or is obtained pursuant to an induced
 24 abortion, and—

25 “(1) the donation will be or is made pursuant
 26 to a promise to the donating individual that the do-

1 nated tissue will be transplanted into a recipient
2 specified by such individual;

3 “(2) the donated tissue will be transplanted
4 into a relative of the donating individual; or

5 “(3) the person who solicits or knowingly ac-
6 quires, receives, or accepts the donation has provided
7 valuable consideration for the costs associated with
8 such abortion.

9 “(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

10 “(1) IN GENERAL.—Any person who violates
11 subsection (a) or (b) shall be fined in accordance
12 with title 18, United States Code, subject to para-
13 graph (2), or imprisoned for not more than 10
14 years, or both.

15 “(2) PENALTIES APPLICABLE TO PERSONS RE-
16 CEIVING CONSIDERATION.—With respect to the im-
17 position of a fine under paragraph (1), if the person
18 involved violates subsection (a) or (b)(3), a fine shall
19 be imposed in an amount not less than twice the
20 amount of the valuable consideration received.

21 “(d) DEFINITIONS.—For purposes of this section:

22 “(1) The term ‘human fetal tissue’ has the
23 meaning given such term in section 498A(f).

1 “(2) The term ‘interstate commerce’ has the
2 meaning given such term in section 201(b) of the
3 Federal Food, Drug, and Cosmetic Act.

4 “(3) The term ‘valuable consideration’ does not
5 include reasonable payments associated with the
6 transportation, implantation, processing, preserva-
7 tion, quality control, or storage of human fetal
8 tissue.”.

9 **SEC. 113. NULLIFICATION OF MORATORIUM.**

10 (a) IN GENERAL.—Except as provided in subsection
11 (c), no official of the executive branch may impose a policy
12 that the Department of Health and Human Services is
13 prohibited from conducting or supporting any research on
14 the transplantation of human fetal tissue for therapeutic
15 purposes. Such research shall be carried out in accordance
16 with section 498A of the Public Health Service Act (as
17 added by section 111 of this Act), without regard to any
18 such policy that may have been in effect prior to the date
19 of the enactment of this Act.

20 (b) PROHIBITION AGAINST WITHHOLDING OF FUNDS
21 IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

22 (1) IN GENERAL.—In the case of any proposal
23 for research on the transplantation of human fetal
24 tissue for therapeutic purposes, the Secretary of

1 Health and Human Services may not withhold funds
2 for the research if—

3 (A) the research has been approved for
4 purposes of section 492A(a) of the Public
5 Health Service Act (as added by section 101 of
6 this Act);

7 (B) the research will be carried out in ac-
8 cordance with section 498A of such Act (as
9 added by section 111 of this Act); and

10 (C) there are reasonable assurances that
11 the research will not utilize any human fetal tis-
12 sue that has been obtained in violation of sec-
13 tion 498B(a) of such Act (as added by section
14 112 of this Act).

15 (2) STANDING APPROVAL REGARDING ETHICAL
16 STATUS.—In the case of any proposal for research
17 on the transplantation of human fetal tissue for
18 therapeutic purposes, the issuance in December
19 1988 of the Report of the Human Fetal Tissue
20 Transplantation Research Panel shall be deemed to
21 be a report—

22 (A) issued by an ethics advisory board pur-
23 suant to section 492A(b)(4)(B)(ii) of the Public
24 Health Service Act (as added by section 101 of
25 this Act); and

1 (B) finding, on a basis that is neither arbitrary nor capricious, that there are no ethical grounds for withholding funds for the research.

2 (c) AUTHORITY FOR WITHHOLDING FUNDS FROM
3 RESEARCH.—In the case of any research on the transplan-
4 tation of human fetal tissue for therapeutic purposes, the
5 Secretary of Health and Human Services may withhold
6 funds for the research if any of the conditions specified
7 in any of subparagraphs (A) through (C) of subsection
8 (b)(1) are not met with respect to the research.

9 (d) DEFINITION.—For purposes of this section, the
10 term “human fetal tissue” has the meaning given such
11 term in section 498A(f) of the Public Health Service Act
12 (as added by section 111 of this Act).

13 **SEC. 114. REPORT BY GENERAL ACCOUNTING OFFICE ON**
14 **ADEQUACY OF REQUIREMENTS.**

15 (a) IN GENERAL.—With respect to research on the
16 transplantation of human fetal tissue for therapeutic pur-
17 poses, the Comptroller General of the United States shall
18 conduct an audit for the purpose of determining—

19 (1) whether and to what extent such research
20 conducted or supported by the Secretary of Health
21 and Human Services has been conducted in accord-
22 ance with section 498A of the Public Health Service
23 Act (as added by section 111 of this Act); and
24
25

1 (2) whether and to what extent there have been
2 violations of section 498B of such Act (as added by
3 section 112 of this Act).

4 (b) REPORT.—Not later than May 19, 1995, the
5 Comptroller General of the United States shall complete
6 the audit required in subsection (a) and submit to the
7 Committee on Energy and Commerce of the House of
8 Representatives, and to the Committee on Labor and
9 Human Resources of the Senate, a report describing the
10 findings made pursuant to the audit.

11 **PART III—MISCELLANEOUS REPEALS**

12 **SEC. 121. REPEALS.**

13 (a) CERTAIN BIOMEDICAL ETHICS BOARD.—Title III
14 of the Public Health Service Act (42 U.S.C. 241 et seq.)
15 is amended by striking part J.

16 (b) OTHER REPEALS.—Part G of title IV of the Pub-
17 lic Health Service Act (42 U.S.C. 289 et seq.) is amend-
18 ed—

19 (1) in section 498, by striking subsection (c);
20 and

21 (2) by striking section 499; and

22 (3) by redesignating section 499A as section
23 499.

24 (c) NULLIFICATION OF CERTAIN REGULATION.—The
25 provisions of section 204(d) of part 46 of title 45 of the

1 Code of Federal Regulations (45 CFR 46.204(d)) shall
2 not have any legal effect.

3 **Subtitle B—Clinical Research Eq-**
4 **uity Regarding Women and Mi-**
5 **norities**

6 **PART I—WOMEN AND MINORITIES AS SUBJECTS**
7 **IN CLINICAL RESEARCH**

8 **SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.**

9 Part G of title IV of the Public Health Service Act,
10 as amended by section 101 of this Act, is amended by in-
11 serting after section 492A the following new section:

12 “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL
13 RESEARCH

14 “SEC. 492B. (a) In conducting or supporting clinical
15 research for purposes of this title, the Director of NIH
16 shall, subject to subsection (b), ensure that—

17 “(1) women are included as subjects in each
18 project of such research; and

19 “(2) members of minority groups are included
20 as subjects in such research.

21 “(b) The requirement established in subsection (a)
22 regarding women and members of minority groups shall
23 not apply to a project of clinical research if the inclusion,
24 as subjects in the project, of women and members of mi-
25 nority groups, respectively—

1 “(1) is inappropriate with respect to the health
2 of the subjects;

3 “(2) is inappropriate with respect to the pur-
4 pose of the research; or

5 “(3) is inappropriate under such other cir-
6 cumstances as the Director of NIH may designate.

7 “(c) In the case of any project of clinical research
8 in which women or members of minority groups will under
9 subsection (a) be included as subjects in the research, the
10 Director of NIH shall ensure that the project is designed
11 and carried out in a manner sufficient to provide for a
12 valid analysis of whether the variables being tested in the
13 research affect women or members of minority groups, as
14 the case may be, differently than other subjects in the
15 research.

16 “(d)(1) The Director of NIH, in consultation with the
17 Director of the Office of Research on Women’s Health,
18 shall establish guidelines regarding—

19 “(A) the circumstances under which the inclu-
20 sion of women and minorities in projects of clinical
21 research is inappropriate for purposes of subsection
22 (b);

23 “(B) the manner in which such projects are re-
24 quired to be designed and carried out for purposes
25 of subsection (c), including a specification of the cir-

1 cumstances in which the requirement of such sub-
2 section does not apply on the basis of impracticabil-
3 ity; and

4 “(C) the conduct of outreach programs for the
5 recruitment of women and members of minority
6 groups as subjects in such research.

7 “(2) With respect to the circumstances under which
8 the inclusion of women or members of minority groups (as
9 the case may be) as subjects in clinical research is inap-
10 propriate for purposes of subsection (b), the guidelines es-
11 tablished under paragraph (1)(A)—

12 “(A) shall provide that the costs of such inclu-
13 sion in a project of clinical research is not a permis-
14 sible consideration in determining whether such in-
15 clusion is inappropriate unless the data of com-
16 parable quality regarding women or members of mi-
17 nority groups, respectively, that would be obtained in
18 such project in the event that such inclusion were re-
19 quired will be obtained through other means; and

20 “(B) may provide that such inclusion in a
21 project of clinical research is not required if there is
22 substantial scientific data demonstrating that there
23 is no significant difference between—

1 “(i) the effects that the variables to be
2 studied in the project have on women or mem-
3 bers of minority groups, respectively; and

4 “(ii) the effects that the variables have on
5 the individuals who would serve as subjects in
6 the project in the event that such inclusion were
7 not required.

8 “(3) The guidelines required in paragraph (1) shall
9 be established and published in the Federal Register not
10 later than 120 days after the date of the enactment of
11 the National Institutes of Health Revitalization Act of
12 1993.

13 “(4) For fiscal year 1994 and subsequent fiscal years,
14 the Director of NIH may not approve any proposal of clin-
15 ical research to be conducted or supported by any agency
16 of the National Institutes of Health unless the proposal
17 specifies the manner in which the research will comply
18 with subsection (a).

19 “(e) The advisory council of each national research
20 institute shall annually submit to the Director of NIH and
21 the Director of the institute involved a report describing
22 the manner in which the agency has complied with sub-
23 section (a).”.

1 **SEC. 132. PEER REVIEW.**

2 Section 492 of the Public Health Service Act (42
3 U.S.C. 289a) is amended by adding at the end the follow-
4 ing new subsection:

5 “(c)(1) In technical and scientific peer review under
6 this section of proposals for clinical research, the consider-
7 ation of any such proposal (including the initial consider-
8 ation) shall, except as provided in paragraph (2), include
9 an evaluation of the technical and scientific merit of the
10 proposal regarding compliance with section 492B(a).

11 “(2) Paragraph (1) shall not apply to any proposal
12 for clinical research that, pursuant to subsection (b) of
13 section 492B, is not subject to the requirement of sub-
14 section (a) of such section regarding the inclusion of
15 women and members of minority groups as subjects in
16 clinical research.”.

17 **SEC. 133. APPLICABILITY TO CURRENT PROJECTS.**

18 Section 492B of the Public Health Service Act, as
19 added by section 131 of this Act, shall not apply with re-
20 spect to projects of clinical research for which initial fund-
21 ing was provided prior to the date of the enactment of
22 this Act. With respect to the inclusion of women and mi-
23 norities as subjects in clinical research conducted or sup-
24 ported by the National Institutes of Health, any policies
25 of the Secretary of Health and Human Services regarding
26 such inclusion that are in effect on the day before the date

1 of the enactment of this Act shall continue to apply to
2 the projects referred to in the preceding sentence.

3 **PART II—OFFICE OF RESEARCH ON WOMEN’S**
4 **HEALTH**

5 **SEC. 141. ESTABLISHMENT.**

6 (a) IN GENERAL.—Title IV of the Public Health
7 Service Act, as amended by section 2 of Public Law 101–
8 613, is amended—

9 (1) by redesignating section 486 as section
10 485A;

11 (2) by redesignating parts F through H as
12 parts G through I, respectively; and

13 (3) by inserting after part E the following new
14 part:

15 “PART F—RESEARCH ON WOMEN’S HEALTH

16 “**SEC. 486. OFFICE OF RESEARCH ON WOMEN’S HEALTH.**

17 “(a) ESTABLISHMENT.—There is established within
18 the Office of the Director of NIH an office to be known
19 as the Office of Research on Women’s Health (in this part
20 referred to as the ‘Office’). The Office shall be headed by
21 a director, who shall be appointed by the Director of NIH.

22 “(b) PURPOSE.—The Director of the Office shall—

23 “(1) identify projects of research on women’s
24 health that should be conducted or supported by the
25 national research institutes;

1 “(2) identify multidisciplinary research relating
2 to research on women’s health that should be so con-
3 ducted or supported;

4 “(3) carry out paragraphs (1) and (2) with re-
5 spect to the aging process in women, with priority
6 given to menopause;

7 “(4) promote coordination and collaboration
8 among entities conducting research identified under
9 any of paragraphs (1) through (3);

10 “(5) encourage the conduct of such research by
11 entities receiving funds from the national research
12 institutes;

13 “(6) recommend an agenda for conducting and
14 supporting such research;

15 “(7) promote the sufficient allocation of the re-
16 sources of the national research institutes for con-
17 ducting and supporting such research;

18 “(8) assist in the administration of section
19 492B with respect to the inclusion of women as sub-
20 jects in clinical research; and

21 “(9) prepare the report required in section
22 486B.

23 “(c) COORDINATING COMMITTEE.—

24 “(1) In carrying out subsection (b), the Direc-
25 tor of the Office shall establish a committee to be

1 known as the Coordinating Committee on Research
2 on Women’s Health (hereafter in this subsection re-
3 ferred to as the ‘Coordinating Committee’).

4 “(2) The Coordinating Committee shall be com-
5 posed of the Directors of the national research insti-
6 tutes (or the designees of the Directors).

7 “(3) The Director of the Office shall serve as
8 the chair of the Coordinating Committee.

9 “(4) With respect to research on women’s
10 health, the Coordinating Committee shall assist the
11 Director of the Office in—

12 “(A) identifying the need for such re-
13 search, and making an estimate each fiscal year
14 of the funds needed to adequately support the
15 research;

16 “(B) identifying needs regarding the co-
17 ordination of research activities, including in-
18 tramural and extramural multidisciplinary ac-
19 tivities;

20 “(C) supporting the development of meth-
21 odologies to determine the circumstances in
22 which obtaining data specific to women (includ-
23 ing data relating to the age of women and the
24 membership of women in ethnic or racial

1 groups) is an appropriate function of clinical
2 trials of treatments and therapies;

3 “(D) supporting the development and ex-
4 pansion of clinical trials of treatments and
5 therapies for which obtaining such data has
6 been determined to be an appropriate function;
7 and

8 “(E) encouraging the national research in-
9 stitutes to conduct and support such research,
10 including such clinical trials.

11 “(d) ADVISORY COMMITTEE.—

12 “(1) In carrying out subsection (b), the Direc-
13 tor of the Office shall establish an advisory commit-
14 tee to be known as the Advisory Committee on Re-
15 search on Women’s Health (hereafter in this sub-
16 section referred to as the ‘Advisory Committee’).

17 “(2) The Advisory Committee shall be com-
18 posed of no fewer than 12, and not more than 18
19 individuals, who are not officers or employees of the
20 Federal Government. The Director of the Office
21 shall make appointments to the Advisory Committee
22 from among physicians, practitioners, scientists, and
23 other health professionals, whose clinical practice,
24 research specialization, or professional expertise in-
25 cludes a significant focus on research on women’s

1 health. A majority of the members of the Advisory
2 Committee shall be women.

3 “(3) The Director of the Office shall serve as
4 the chair of the Advisory Committee.

5 “(4) The Advisory Committee shall—

6 “(A) advise the Director of the Office on
7 appropriate research activities to be undertaken
8 by the national research institutes with respect
9 to—

10 “(i) research on women’s health;

11 “(ii) research on gender differences in
12 clinical drug trials, including responses to
13 pharmacological drugs;

14 “(iii) research on gender differences
15 in disease etiology, course, and treatment;

16 “(iv) research on obstetrical and gyne-
17 cological health conditions, diseases, and
18 treatments; and

19 “(v) research on women’s health con-
20 ditions which require a multidisciplinary
21 approach;

22 “(B) report to the Director of the Office
23 on such research;

24 “(C) provide recommendations to such Di-
25 rector regarding activities of the Office (includ-

1 ing recommendations on the development of the
2 methodologies described in subsection (c)(4)(C)
3 and recommendations on priorities in carrying
4 out research described in subparagraph (A));
5 and

6 “(D) assist in monitoring compliance with
7 section 492B regarding the inclusion of women
8 in clinical research.

9 “(5)(A) The Advisory Committee shall prepare
10 a biennial report describing the activities of the
11 Committee, including findings made by the Commit-
12 tee regarding—

13 “(i) compliance with section 492B;

14 “(ii) the extent of expenditures made for
15 research on women’s health by the agencies of
16 the National Institutes of Health; and

17 “(iii) the level of funding needed for such
18 research.

19 “(B) The report required in subparagraph (A)
20 shall be submitted to the Director of NIH for inclu-
21 sion in the report required in section 403.

22 “(e) REPRESENTATION OF WOMEN AMONG RE-
23 SEARCHERS.—The Secretary, acting through the Assist-
24 ant Secretary for Personnel and in collaboration with the
25 Director of the Office, shall determine the extent to which

1 women are represented among senior physicians and sci-
2 entists of the national research institutes and among phy-
3 sicians and scientists conducting research with funds pro-
4 vided by such institutes, and as appropriate, carry out ac-
5 tivities to increase the extent of such representation.

6 “(f) DEFINITIONS.—For purposes of this part:

7 “(1) The term ‘women’s health conditions’, with
8 respect to women of all age, ethnic, and racial
9 groups, means all diseases, disorders, and conditions
10 (including with respect to mental health)—

11 “(A) unique to, more serious, or more
12 prevalent in women;

13 “(B) for which the factors of medical risk
14 or types of medical intervention are different
15 for women, or for which it is unknown whether
16 such factors or types are different for women;
17 or

18 “(C) with respect to which there has been
19 insufficient clinical research involving women as
20 subjects or insufficient clinical data on women.

21 “(2) The term ‘research on women’s health’
22 means research on women’s health conditions, in-
23 cluding research on preventing such conditions.

1 **“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE**
2 **ON RESEARCH ON WOMEN’S HEALTH.**

3 “(a) DATA SYSTEM.—

4 “(1) The Director of NIH, in consultation with
5 the Director of the Office, shall establish a data sys-
6 tem for the collection, storage, analysis, retrieval,
7 and dissemination of information regarding research
8 on women’s health that is conducted or supported by
9 the national research institutes. Information from
10 the data system shall be available through informa-
11 tion systems available to health care professionals
12 and providers, researchers, and members of the
13 public.

14 “(2) The data system established under para-
15 graph (1) shall include a registry of clinical trials of
16 experimental treatments that have been developed
17 for research on women’s health. Such registry shall
18 include information on subject eligibility criteria,
19 sex, age, ethnicity or race, and the location of the
20 trial site or sites. Principal investigators of such
21 clinical trials shall provide this information to the
22 registry within 30 days after it is available. Once a
23 trial has been completed, the principal investigator
24 shall provide the registry with information pertain-
25 ing to the results, including potential toxicities or

1 adverse effects associated with the experimental
2 treatment or treatments evaluated.

3 “(b) CLEARINGHOUSE.—The Director of NIH, in
4 consultation with the Director of the Office and with the
5 National Library of Medicine, shall establish, maintain,
6 and operate a program to provide information on research
7 and prevention activities of the national research institutes
8 that relate to research on women’s health.

9 **“SEC. 486B. BIENNIAL REPORT.**

10 “(a) IN GENERAL.—With respect to research on
11 women’s health, the Director of the Office shall, not later
12 than February 1, 1994, and biennially thereafter, prepare
13 a report—

14 “(1) describing and evaluating the progress
15 made during the preceding 2 fiscal years in research
16 and treatment conducted or supported by the Na-
17 tional Institutes of Health;

18 “(2) describing and analyzing the professional
19 status of women physicians and scientists of such
20 Institutes, including the identification of problems
21 and barriers regarding advancements;

22 “(3) summarizing and analyzing expenditures
23 made by the agencies of such Institutes (and by
24 such Office) during the preceding 2 fiscal years; and

1 “(4) making such recommendations for legisla-
2 tive and administrative initiatives as the Director of
3 the Office determines to be appropriate.

4 “(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR
5 OF NIH.—The Director of the Office shall submit each
6 report prepared under subsection (a) to the Director of
7 NIH for inclusion in the report submitted to the President
8 and the Congress under section 403.”.

9 (b) REQUIREMENT OF SUFFICIENT ALLOCATION OF
10 RESOURCES OF INSTITUTES.—Section 402(b) of the Pub-
11 lic Health Service Act (42 U.S.C. 282(b)) is amended—

12 (1) in paragraph (10), by striking “and” after
13 the semicolon at the end;

14 (2) in paragraph (11), by striking the period at
15 the end and inserting “; and”; and

16 (3) by inserting after paragraph (11) the fol-
17 lowing new paragraph:

18 “(12) after consultation with the Director of
19 the Office of Research on Women’s Health, shall en-
20 sure that resources of the National Institutes of
21 Health are sufficiently allocated for projects of re-
22 search on women’s health that are identified under
23 section 486(b).”.

1 **Subtitle C—Scientific Integrity**

2 **SEC. 151. ESTABLISHMENT OF OFFICE OF SCIENTIFIC IN-**
3 **TEGRITY.**

4 (a) IN GENERAL.—Section 493 of the Public Health
5 Service Act (42 U.S.C. 289b) is amended to read as fol-
6 lows:

7 “OFFICE OF SCIENTIFIC INTEGRITY

8 “SEC. 493. (a) ESTABLISHMENT.—

9 “(1) IN GENERAL.—Not later than 90 days
10 after the date of enactment of this section, the Sec-
11 retary shall establish an office to be known as the
12 Office of Scientific Integrity (hereafter referred to in
13 this section as the ‘Office’), which shall be estab-
14 lished as an independent entity in the Department
15 of Health and Human Services.

16 “(2) DIRECTOR.—The Office shall be headed by
17 a Director, who shall be appointed by the Secretary,
18 be experienced and specially trained in the conduct
19 of research, and have experience in the conduct of
20 investigations of scientific misconduct. The Sec-
21 retary shall carry out this section acting through the
22 Director of the Office. The Director shall report to
23 the Secretary.

24 “(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS
25 CONDITION OF FUNDING FOR RESEARCH.—The Secretary

1 shall by regulation require that each entity that applies
2 for a grant, contract, or cooperative agreement under this
3 Act for any project or program that involves the conduct
4 of biomedical or behavioral research submit in or with its
5 application for such grant, contract, or cooperative agree-
6 ment assurances satisfactory to the Secretary that such
7 entity—

8 “(1) has established (in accordance with regula-
9 tions which the Secretary shall prescribe) an admin-
10 istrative process to review reports of scientific mis-
11 conduct in connection with biomedical and behav-
12 ioral research conducted at or sponsored by such en-
13 tity; and

14 “(2) will report to the Director any investiga-
15 tion of alleged scientific misconduct in connection
16 with projects for which funds have been made avail-
17 able under this Act that appears substantial.

18 “(c) PROCESS FOR RESPONSE OF DIRECTOR.—The
19 Secretary shall establish by regulation a process to be fol-
20 lowed by the Director for the prompt and appropriate—

21 “(1) response to information provided to the
22 Director respecting scientific misconduct in connec-
23 tion with projects for which funds have been made
24 available under this Act;

1 “(2) receipt of reports by the Director of such
2 information from recipients of funds under this Act;

3 “(3) conduct of investigations, when appro-
4 priate; and

5 “(4) taking of other actions, including appro-
6 priate remedies, with respect to such misconduct.

7 “(d) MONITORING BY DIRECTOR.—The Secretary
8 shall by regulation establish procedures for the Director
9 to monitor administrative processes and investigations
10 that have been established or carried out under this sec-
11 tion.

12 “(e) EFFECT ON PRESENT INVESTIGATIONS.—Noth-
13 ing in this section shall affect investigations which have
14 been or will be commenced prior to the promulgation of
15 final regulations under this section.”.

16 (b) ESTABLISHMENT OF DEFINITION OF SCIENTIFIC
17 MISCONDUCT.—Not later than 90 days after the date on
18 which the report required under section 152(d) is submit-
19 ted to the Secretary of Health and Human Services, such
20 Secretary shall by regulation establish a definition for the
21 term “scientific misconduct” for purposes of section 493
22 of the Public Health Service Act, as amended by sub-
23 section (a) of this section.

1 **SEC. 152. COMMISSION ON SCIENTIFIC INTEGRITY.**

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services shall establish a commission to be known
4 as the Commission on Scientific Integrity (in this section
5 referred to as the “Commission”).

6 (b) DUTIES.—The Commission shall develop rec-
7 ommendations for the Secretary of Health and Human
8 Services on the administration of section 493 of the Public
9 Health Service Act (as amended and added by section 151
10 of this Act).

11 (c) COMPOSITION.—The Commission shall be com-
12 posed of 12 members to be appointed by the Secretary
13 of Health and Human Services from among individuals
14 who are not officers or employees of the United States.
15 Of the members appointed to the Commission—

16 (1) three shall be scientists with substantial ac-
17 complishments in biomedical or behavioral research;

18 (2) three shall be individuals with experience in
19 investigating allegations of misconduct with respect
20 to scientific research;

21 (3) three shall be representatives of institutions
22 of higher education at which biomedical or behav-
23 ioral research is conducted; and

24 (4) three shall be individuals who are not de-
25 scribed in paragraphs (1), (2), or (3), at least one

1 of whom shall be an attorney and at least one of
2 whom shall be an ethicist.

3 (d) REPORT.—Not later than 120 days after the date
4 of enactment of this section, the Commission shall prepare
5 and submit to the Secretary of Health and Human Serv-
6 ices, the Committee on Energy and Commerce of the
7 House of Representatives, and the Committee on Labor
8 and Human Resources of the Senate, a report containing
9 the recommendations developed under subsection (b).

10 **SEC. 153. PROTECTION OF WHISTLEBLOWERS.**

11 Section 493 of the Public Health Service Act, as
12 amended by section 151 of this Act, is amended by adding
13 at the end the following new subsection:

14 “(f) PROTECTION OF WHISTLEBLOWERS.—

15 “(1) IN GENERAL.—In the case of any entity
16 required to establish administrative processes under
17 subsection (b), the Secretary shall by regulation es-
18 tablish standards for preventing, and for responding
19 to the occurrence of retaliation by such entity, its of-
20 ficials or agents, against an employee in the terms
21 and conditions of employment in response to the em-
22 ployee having in good faith—

23 “(A) made an allegation that the entity, its
24 officials or agents, has engaged in or failed to

1 adequately respond to an allegation of scientific
2 misconduct; or

3 “(B) cooperated with an investigation of
4 such an allegation.

5 “(2) MONITORING BY SECRETARY.—The Sec-
6 retary shall establish by regulation procedures for
7 the Director to monitor the implementation of the
8 standards established by an entity under paragraph
9 (1) for the purpose of determining whether the pro-
10 cedures have been established, and are being uti-
11 lized, in accordance with the standards established
12 under such paragraph.

13 “(3) NONCOMPLIANCE.—The Secretary shall by
14 regulation establish remedies for noncompliance by
15 an entity, its officials or agents, which has engaged
16 in retaliation in violation of the standards estab-
17 lished under paragraph (1). Such remedies may in-
18 clude termination of funding provided by the Sec-
19 retary for such project or recovery of funding being
20 provided by the Secretary for such project, or other
21 actions as appropriate.

22 “(4) FINAL RULE FOR REGULATIONS.—The
23 Secretary shall issue a final rule for the regulations
24 required in paragraph (1) not later than 180 days

1 after the date of the enactment of the National In-
 2 stitutes of Health Revitalization Act of 1993.

3 “(5) REQUIRED AGREEMENTS.—For any fiscal
 4 year beginning after the date on which the regula-
 5 tions required in paragraph (1) are issued, the Sec-
 6 retary may not provide a grant, cooperative agree-
 7 ment, or contract under this Act for biomedical or
 8 behavioral research unless the entity seeking such fi-
 9 nancial assistance agrees that the entity—

10 “(A) will maintain the procedures de-
 11 scribed in the regulations; and

12 “(B) will otherwise be subject to the regu-
 13 lations.”.

14 **SEC. 154. REQUIREMENT OF REGULATIONS REGARDING**
 15 **PROTECTION AGAINST FINANCIAL CON-**
 16 **FLICTS OF INTEREST IN CERTAIN PROJECTS**
 17 **OF RESEARCH.**

18 Part H of title IV of the Public Health Service Act,
 19 as redesignated by section 141(a)(2) of this Act, is amend-
 20 ed by inserting after section 493 the following new section:

21 “PROTECTION AGAINST FINANCIAL CONFLICTS OF
 22 INTEREST IN CERTAIN PROJECTS OF RESEARCH

23 “SEC. 493A. (a) ISSUANCE OF REGULATIONS.—

24 “(1) IN GENERAL.—The Secretary shall define
 25 by regulation, the specific circumstances that con-
 26 stitute the existence of a financial interest in a

1 project on the part of an entity or individual that
2 will, or may be reasonably expected to, create a bias
3 in favor of obtaining results in such project that are
4 consistent with such financial interest. Such defini-
5 tion shall apply uniformly to each entity or individ-
6 ual conducting a research project under this Act. In
7 the case of any entity or individual receiving assist-
8 ance from the Secretary for a project of research de-
9 scribed in paragraph (2), the Secretary shall by reg-
10 ulation establish standards for responding to, includ-
11 ing managing, reducing, or eliminating, the existence
12 of such a financial interest. The entity may adopt
13 individualized procedures for implementing the
14 standards.

15 “(2) RELEVANT PROJECTS.—A project of re-
16 search referred to in paragraph (1) is a project of
17 clinical research whose purpose is to evaluate the
18 safety or effectiveness of a drug, medical device, or
19 treatment and for which such entity is receiving as-
20 sistance from the Secretary.

21 “(3) IDENTIFYING AND REPORTING TO THE DI-
22 RECTOR.—The Secretary shall ensure that the
23 standards established under paragraph (1) specify
24 that as a condition of receiving assistance from the

1 Secretary for the project involved, an entity de-
2 scribed in such subsection is required—

3 “(A) to have in effect at the time the en-
4 tity applies for the assistance and throughout
5 the period during which the assistance is re-
6 ceived, a process for identifying such financial
7 interests as defined in paragraph (1) that exist
8 regarding the project; and

9 “(B) to report to the Director such finan-
10 cial interest as defined in paragraph (1) identi-
11 fied by the entity and how any such financial
12 interest identified by the entity will be managed
13 or eliminated such that the project in question
14 will be protected from bias that may stem from
15 such financial interest.

16 “(4) MONITORING OF PROCESS.—The Secretary
17 shall monitor the establishment and conduct of the
18 process established by an entity pursuant to para-
19 graph (1).

20 “(5) RESPONSE.—In any case in which the Sec-
21 retary determines that an entity has failed to comply
22 with paragraph (3) regarding a project of research
23 described in paragraph (1), the Secretary—

24 “(A) shall require that, as a condition of
25 receiving assistance, the entity disclose the ex-

1 istence of a financial interest as defined in
2 paragraph (1) in each public presentation of the
3 results of such project; and

4 “(B) may take such other actions as the
5 Secretary determines to be appropriate.

6 “(6) DEFINITION.—As used in this section:

7 “(A) The term ‘financial interest’ includes
8 the receipt of consulting fees or honoraria and
9 the ownership of stock or equity.

10 “(B) The term ‘assistance’, with respect to
11 conducting a project of research, means a
12 grant, contract, or cooperative agreement.

13 “(b) FINAL RULE FOR REGULATIONS.—The Sec-
14 retary shall issue a final rule for the regulations required
15 in subsection (a) not later than 180 days after the date
16 of the enactment of the National Institutes of Health Re-
17 vitalization Act of 1993.”.

18 **SEC. 155. EFFECTIVE DATES.**

19 (a) IN GENERAL.—The amendments made by this
20 subtitle shall become effective on the date that occurs 180
21 days after the date on which the final rule required under
22 section 493(f)(4) of the Public Health Service Act, as
23 amended by sections 151 and 153, is published in the Fed-
24 eral Register.

1 (b) AGREEMENTS AS A CONDITION OF FUNDING.—
2 The requirements of subsection (f)(5) of section 493 of
3 the Public Health Service Act, as amended by sections 151
4 and 153, with respect to agreements as a condition of
5 funding shall not be effective in the case of projects of
6 research for which initial funding under the Public Health
7 Service Act was provided prior to the effective date de-
8 scribed in subsection (a).

9 **TITLE II—NATIONAL INSTITUTES**
10 **OF HEALTH IN GENERAL**

11 **SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINA-**
12 **TION.**

13 Section 402(f) of the Public Health Service Act (42
14 U.S.C. 282(f)) is amended by striking “other public and
15 private entities.” and all that follows through the end and
16 inserting “other public and private entities, including ele-
17 mentary, secondary, and post-secondary schools. The As-
18 sociate Director shall—

19 “(1) annually review the efficacy of existing
20 policies and techniques used by the national research
21 institutes to disseminate the results of disease pre-
22 vention and behavioral research programs;

23 “(2) recommend, coordinate, and oversee the
24 modification or reconstruction of such policies and
25 techniques to ensure maximum dissemination, using

1 advanced technologies to the maximum extent prac-
2 ticable, of research results to such entities; and

3 “(3) annually prepare and submit to the Direc-
4 tor of NIH a report concerning the prevention and
5 dissemination activities undertaken by the Associate
6 Director, including—

7 “(A) a summary of the Associate Direc-
8 tor’s review of existing dissemination policies
9 and techniques together with a detailed state-
10 ment concerning any modification or restructur-
11 ing, or recommendations for modification or re-
12 structuring, of such policies and techniques;
13 and

14 “(B) a detailed statement of the expendi-
15 tures made for the prevention and dissemina-
16 tion activities reported on and the personnel
17 used in connection with such activities.”.

18 **SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-**
19 **ING CERTAIN STATES AND RESEARCHERS.**

20 Section 402 of the Public Health Service Act (42
21 U.S.C. 282) is amended by adding at the end the following
22 new subsection:

23 “(g)(1)(A) In the case of entities described in sub-
24 paragraph (B), the Director of NIH, acting through the
25 Director of the National Center for Research Resources,

1 shall establish a program to enhance the competitiveness
2 of such entities in obtaining funds from the national re-
3 search institutes for conducting biomedical and behavioral
4 research.

5 “(B) The entities referred to in subparagraph (A) are
6 entities that conduct biomedical and behavioral research
7 and are located in a State in which the aggregate success
8 rate for applications to the national research institutes for
9 assistance for such research by the entities in the State
10 has historically constituted a low success rate of obtaining
11 such funds, relative to such aggregate rate for such enti-
12 ties in other States.

13 “(C) With respect to enhancing competitiveness for
14 purposes of subparagraph (A), the Director of NIH, in
15 carrying out the program established under such subpara-
16 graph, may—

17 “(i) provide technical assistance to the entities
18 involved, including technical assistance in the prepa-
19 ration of applications for obtaining funds from the
20 national research institutes;

21 “(ii) assist the entities in developing a plan for
22 biomedical or behavioral research proposals; and

23 “(iii) assist the entities in implementing such
24 plan.

1 “(2) The Director of NIH shall establish a program
2 of supporting projects of biomedical or behavioral research
3 whose principal researchers are individuals who have not
4 previously served as the principal researchers of such
5 projects supported by the Director.”.

6 **SEC. 203. CHILDREN’S VACCINE INITIATIVE.**

7 Part A of title IV of the Public Health Service Act
8 (42 U.S.C. 281 et seq.) is amended by adding at the end
9 the following new section:

10 “CHILDREN’S VACCINE INITIATIVE

11 “SEC. 404. (a) DEVELOPMENT OF NEW VACCINES.—
12 The Secretary, in consultation with the Director of the
13 National Vaccine Program under title XXI and acting
14 through the Directors of the National Institute for Allergy
15 and Infectious Diseases, the National Institute for Child
16 Health and Human Development, the National Institute
17 for Aging, and other public and private programs, shall
18 carry out activities, which shall be consistent with the
19 global Children’s Vaccine Initiative, to develop affordable
20 new and improved vaccines to be used in the United States
21 and in the developing world that will increase the efficacy
22 and efficiency of the prevention of infectious diseases. In
23 carrying out such activities, the Secretary shall, to the ex-
24 tent practicable, develop and make available vaccines that
25 require fewer contacts to deliver, that can be given early
26 in life, that provide long lasting protection, that obviate

1 refrigeration, needles and syringes, and that protect
2 against a larger number of diseases.

3 “(b) REPORT.—In the report required in section
4 2104, the Secretary, acting through the Director of the
5 National Vaccine Program under title XXI, shall include
6 information with respect to activities and the progress
7 made in implementing the provisions of this section and
8 achieving its goals.

9 “(c) AUTHORIZATION OF APPROPRIATIONS.—In ad-
10 dition to any other amounts authorized to be appropriated
11 for activities of the type described in this section, there
12 are authorized to be appropriated to carry out this section
13 \$50,000,000 for fiscal year 1994, and such sums as may
14 be necessary for each of the fiscal years 1995 and 1996.”.

15 **SEC. 204. PLAN FOR USE OF ANIMALS IN RESEARCH.**

16 (a) IN GENERAL.—Part A of title IV of the Public
17 Health Service Act, as amended by section 203 of this Act,
18 is amended by adding at the end the following new section:

19 “PLAN FOR USE OF ANIMALS IN RESEARCH

20 “SEC. 404A. (a) The Director of NIH, after consulta-
21 tion with the committee established under subsection (e),
22 shall prepare a plan—

23 “(1) for the National Institutes of Health to
24 conduct or support research into—

1 “(A) methods of biomedical research and
2 experimentation that do not require the use of
3 animals;

4 “(B) methods of such research and experi-
5 mentation that reduce the number of animals
6 used in such research; and

7 “(C) methods of such research and experi-
8 mentation that produce less pain and distress in
9 such animals;

10 “(2) for establishing the validity and reliability
11 of the methods described in paragraph (1);

12 “(3) for encouraging the acceptance by the sci-
13 entific community of such methods that have been
14 found to be valid and reliable; and

15 “(4) for training scientists in the use of such
16 methods that have been found to be valid and reli-
17 able.

18 “(b) Not later than October 1, 1993, the Director
19 of NIH shall submit to the Committee on Energy and
20 Commerce of the House of Representatives, and to the
21 Committee on Labor and Human Resources of the Senate,
22 the plan required in subsection (a) and shall begin imple-
23 mentation of the plan.

24 “(c) The Director of NIH shall periodically review,
25 and as appropriate, make revisions in the plan required

1 under subsection (a). A description of any revision made
2 in the plan shall be included in the first biennial report
3 under section 403 that is submitted after the revision is
4 made.

5 “(d) The Director of NIH shall take such actions as
6 may be appropriate to convey to scientists and others who
7 use animals in biomedical or behavioral research or experi-
8 mentation information respecting the methods found to be
9 valid and reliable under subsection (a)(2).

10 “(e)(1) The Director of NIH shall establish within
11 the National Institutes of Health a committee to be known
12 as the Interagency Coordinating Committee on the Use
13 of Animals in Research (hereafter in this subsection re-
14 ferred to as the ‘Committee’).

15 “(2) The Committee shall provide advice to the Direc-
16 tor of NIH on the preparation of the plan required in sub-
17 section (a).

18 “(3) The Committee shall be composed of—

19 “(A) the Directors of each of the national re-
20 search institutes and the Director of the Center for
21 Research Resources (or the designees of such Direc-
22 tors); and

23 “(B) representatives of the Environmental Pro-
24 tection Agency, the Food and Drug Administration,
25 the Consumer Product Safety Commission, the Na-

(b) CONFORMING AMENDMENT.—Section 4 of the Health Research Extension Act of 1985 (Public Law 99–158; 99 Stat. 880) is repealed.

7 **SEC. 205. INCREASED PARTICIPATION OF WOMEN AND DIS-**
8 **ADVANTAGED INDIVIDUALS IN FIELDS OF**
9 **BIOMEDICAL AND BEHAVIORAL RESEARCH.**

Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection:

“(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, may conduct and support programs for research, research training, recruitment, and other activities to provide for an increase in the number of women and individuals from disadvantaged backgrounds in the fields of biomedical and behavioral research.”.

20 SEC. 206. REQUIREMENTS REGARDING SURVEYS OF SEX-
21 UAL BEHAVIOR.

22 Part A of title IV of the Public Health Service Act,
23 as amended by section 204 of this Act, is amended by add-
24 ing at the end the following new section:

1 “REQUIREMENTS REGARDING SURVEYS OF SEXUAL
2 BEHAVIOR

3 “SEC. 404B. With respect to any survey of human
4 sexual behavior proposed to be conducted or supported
5 through the National Institutes of Health, the survey may
6 not be carried out unless—

“(1) the proposal has undergone review in accordance with any applicable requirements of sections 491 and 492; and

10 “(2) the Secretary, in accordance with section
11 492A, makes a determination that the information
12 expected to be obtained through the survey will as-
13 sist—

14 “(A) in reducing the incidence of sexually
15 transmitted diseases, the incidence of infection
16 with the human immunodeficiency virus, or the
17 incidence of any other infectious disease; or

18 “(B) in improving reproductive health or
19 other conditions of health.”.

20 SEC. 207. DISCRETIONARY FUND OF DIRECTOR OF NA-
21 TIONAL INSTITUTES OF HEALTH.

22 Section 402 of the Public Health Service Act, as
23 amended by section 205 of this Act, is amended by adding
24 at the end the following new subsection:

1 “(i)(1) There is established a fund, consisting of
2 amounts appropriated under paragraph (3) and made
3 available for the fund, for use by the Director of NIH to
4 carry out the activities authorized in this Act for the Na-
5 tional Institutes of Health. The purposes for which such
6 fund may be expended include—

7 “(A) providing for research on matters that
8 have not received significant funding relative to
9 other matters, responding to new issues and sci-
10 entific emergencies, and acting on research opportu-
11 nities of high priority;

12 “(B) supporting research that is not exclusively
13 within the authority of any single agency of such In-
14 stitutes; and

15 “(C) purchasing or renting equipment and
16 quarters for activities of such Institutes.

17 “(2) Not later than February 10 of each fiscal year,
18 the Secretary shall submit to the Committee on Energy
19 and Commerce of the House of Representatives, and to
20 the Committee on Labor and Human Resources of the
21 Senate, a report describing the activities undertaken and
22 expenditures made under this section during the preceding
23 fiscal year. The report may contain such comments of the
24 Secretary regarding this section as the Secretary deter-
25 mines to be appropriate.

1 “(3) For the purpose of carrying out this subsection,
2 there are authorized to be appropriated \$25,000,000 for
3 fiscal year 1994, and such sums as may be necessary for
4 each of the fiscal years 1995 and 1996.”.

5 **SEC. 208. MISCELLANEOUS PROVISIONS.**

6 (a) TERM OF OFFICE FOR MEMBERS OF ADVISORY
7 COUNCILS.—Section 406(c) of the Public Health Service
8 Act (42 U.S.C. 284a(c)) is amended in the second sen-
9 tence by striking “until a successor has been appointed”
10 and inserting the following: “for 180 days after the date
11 of such expiration”.

12 (b) LITERACY REQUIREMENTS.—Section 402(e) of
13 the Public Health Service Act (42 U.S.C. 282(e)) is
14 amended—

15 (1) in paragraph (3), by striking “and” at the
16 end;

17 (2) in paragraph (4), by striking the period and
18 inserting “; and”; and

19 (3) by adding at the end thereof the following
20 new paragraph:

21 “(5) ensure that, after January 1, 1994, at
22 least one-half of all new or revised health education
23 and promotion materials developed or funded by the
24 National Institutes of Health is in a form that does
25 not exceed a level of functional literacy, as defined

1 in the National Literacy Act of 1991 (Public Law
2 102-73).”.

3 (c) DAY CARE REGARDING CHILDREN OF EMPLOY-
4 EES.—Section 402 of the Public Health Service Act, as
5 amended by section 207 of this Act, is amended by adding
6 at the end the following new subsection:

7 “(i)(1) The Director of NIH may establish a program
8 to provide day care service for the employees of the Na-
9 tional Institutes of Health similar to those services pro-
10 vided by other Federal agencies (including the availability
11 of day care service on a 24-hour-a-day basis).

12 “(2) Any day care provider at the National Institutes
13 of Health shall establish a sliding scale of fees that takes
14 into consideration the income and needs of the employee.

15 “(3) For purposes regarding the provision of day care
16 service, the Director of NIH may enter into rental or lease
17 purchase agreements.”.

18 **TITLE III—GENERAL PROVI-**
19 **SIONS RESPECTING NA-**
20 **TIONAL RESEARCH INSTI-**
21 **TUTES**

22 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**
23 **OF NATIONAL RESEARCH INSTITUTES.**

24 (a) ESTABLISHMENT OF GENERAL AUTHORITY RE-
25 GARDING DIRECT FUNDING.—

1 (1) IN GENERAL.—Section 405(b)(2) of the
2 Public Health Service Act (42 U.S.C. 284(b)(2)) is
3 amended—

4 (A) in subparagraph (A), by striking
5 “and” after the semicolon at the end;

6 (B) in subparagraph (B), by striking the
7 period at the end and inserting “; and”; and

8 (C) by adding at the end the following new
9 subparagraph:

10 “(C) shall receive from the President and the
11 Office of Management and Budget directly all funds
12 appropriated by the Congress for obligation and ex-
13 penditure by the Institute.”.

14 (2) CONFORMING AMENDMENT.—Section
15 413(b)(9) of the Public Health Service Act (42
16 U.S.C. 285a–2(b)(9)) is amended—

17 (A) by striking “(A)” after “(9)”; and

18 (B) by striking “advisory council;” and all
19 that follows and inserting “advisory council.”.

20 (b) APPOINTMENT AND DURATION OF TECHNICAL
21 AND SCIENTIFIC PEER REVIEW GROUPS.—Section 405(c)
22 of the Public Health Service Act (42 U.S.C. 284(c)) is
23 amended—

24 (1) by amending paragraph (3) to read as fol-
25 lows:

1 “(3) may, in consultation with the advisory
 2 council for the Institute and with the approval of the
 3 Director of NIH—

4 “(A) establish technical and scientific peer
 5 review groups in addition to those appointed
 6 under section 402(b)(6); and

7 “(B) appoint the members of peer review
 8 groups established under subparagraph (A);
 9 and”; and

10 (2) by adding after and below paragraph (4)
 11 the following:

12 “The Federal Advisory Committee Act shall not apply to
 13 the duration of a peer review group appointed under para-
 14 graph (3).”.

15 **SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,**
 16 **PAGET’S DISEASE, AND RELATED BONE DIS-**
 17 **ORDERS.**

18 Part B of title IV of the Public Health Service Act
 19 (42 U.S.C. 284 et seq.), as amended by section 121(b)
 20 of Public Law 102-321 (106 Stat. 358), is amended by
 21 adding at the end the following new section:

22 “RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND
 23 RELATED BONE DISORDERS

24 “SEC. 410. (a) ESTABLISHMENT.—The Directors of
 25 the National Institute of Arthritis and Musculoskeletal
 26 and Skin Diseases, the National Institute on Aging, and

1 the National Institute of Diabetes, Digestive and Kidney
2 Diseases, shall expand and intensify the programs of such
3 Institutes with respect to research and related activities
4 concerning osteoporosis, Paget's disease, and related bone
5 disorders.

6 “(b) COORDINATION.—The Directors referred to in
7 subsection (a) shall jointly coordinate the programs re-
8 ferred to in such subsection and consult with the Arthritis
9 and Musculoskeletal Diseases Interagency Coordinating
10 Committee and the Interagency Task Force on Aging Re-
11 search.

12 “(c) INFORMATION CLEARINGHOUSE.—

13 “(1) IN GENERAL.—In order to assist in carry-
14 ing out the purpose described in subsection (a), the
15 Director of NIH shall provide for the establishment
16 of an information clearinghouse on osteoporosis and
17 related bone disorders to facilitate and enhance
18 knowledge and understanding on the part of health
19 professionals, patients, and the public through the
20 effective dissemination of information.

21 “(2) ESTABLISHMENT THROUGH GRANT OR
22 CONTRACT.—For the purpose of carrying out para-
23 graph (1), the Director of NIH shall enter into a
24 grant, cooperative agreement, or contract with a
25 nonprofit private entity involved in activities regard-

1 ing the prevention and control of osteoporosis and
2 related bone disorders.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated \$40,000,000 for fiscal year 1994, and
6 such sums as may be necessary for each of the fiscal years
7 1995 and 1996.”.

8 **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**
9 **FOR TRAUMA RESEARCH.**

10 (a) IN GENERAL.—Title XII of the Public Health
11 Service Act (42 U.S.C. 300d et seq.) is amended by adding
12 at the end the following part:

13 “PART E—INTERAGENCY PROGRAM FOR TRAUMA
14 RESEARCH

15 **“SEC. 1251. ESTABLISHMENT OF PROGRAM.**

16 “(a) IN GENERAL.—The Secretary, acting through
17 the Director of the National Institutes of Health (here-
18 after in this section referred to as the ‘Director’), shall
19 establish a comprehensive program of conducting basic
20 and clinical research on trauma (hereafter in this section
21 referred to as the ‘Program’). The Program shall include
22 research regarding the diagnosis, treatment, rehabilita-
23 tion, and general management of trauma.

24 (b) PLAN FOR PROGRAM.—

1 “(1) IN GENERAL.—The Director, in consulta-
2 tion with the Trauma Research Interagency Coordi-
3 nating Committee established under subsection (g),
4 shall establish and implement a plan for carrying
5 out the activities of the Program, including the ac-
6 tivities described in subsection (d). All such activities
7 shall be carried out in accordance with the plan. The
8 plan shall be periodically reviewed, and revised as
9 appropriate.

10 “(2) SUBMISSION TO CONGRESS.—Not later
11 than June 1, 1993, the Director shall submit the
12 plan required in paragraph (1) to the Committee on
13 Energy and Commerce of the House of Representa-
14 tives, and to the Committee on Labor and Human
15 Resources of the Senate, together with an estimate
16 of the funds needed for each of the fiscal years 1994
17 through 1996 to implement the plan.

18 “(c) PARTICIPATING AGENCIES; COORDINATION AND
19 COLLABORATION.—The Director—

20 “(1) shall provide for the conduct of activities
21 under the Program by the Directors of the agencies
22 of the National Institutes of Health involved in re-
23 search with respect to trauma;

24 “(2) shall ensure that the activities of the Pro-
25 gram are coordinated among such agencies; and

1 “(3) shall, as appropriate, provide for collabora-
2 tion among such agencies in carrying out such ac-
3 tivities.

4 “(d) CERTAIN ACTIVITIES OF PROGRAM.—The Pro-
5 gram shall include—

6 “(1) studies with respect to all phases of trau-
7 ma care, including prehospital, resuscitation, sur-
8 gical intervention, critical care, infection control,
9 wound healing, nutritional care and support, and
10 medical rehabilitation care;

11 “(2) basic and clinical research regarding the
12 response of the body to trauma and the acute treat-
13 ment and medical rehabilitation of individuals who
14 are the victims of trauma; and

15 “(3) basic and clinical research regarding trau-
16 ma care for pediatric and geriatric patients.

17 “(e) MECHANISMS OF SUPPORT.—In carrying out the
18 Program, the Director, acting through the Directors of the
19 agencies referred to in subsection (c)(1), may make grants
20 to public and nonprofit entities, including designated trau-
21 ma centers.

22 “(f) RESOURCES.—The Director shall assure the
23 availability of appropriate resources to carry out the Pro-
24 gram, including the plan established under subsection (b)
25 (including the activities described in subsection (d)).

1 “(g) COORDINATING COMMITTEE.—

2 “(1) IN GENERAL.—There shall be established
3 a Trauma Research Interagency Coordinating Com-
4 mittee (hereafter in this section referred to as the
5 ‘Coordinating Committee’).

6 “(2) DUTIES.—The Coordinating Committee
7 shall make recommendations regarding—

8 “(A) the activities of the Program to be
9 carried out by each of the agencies represented
10 on the Committee and the amount of funds
11 needed by each of the agencies for such activi-
12 ties; and

13 “(B) effective collaboration among the
14 agencies in carrying out the activities.

15 “(3) COMPOSITION.—The Coordinating Com-
16 mittee shall be composed of the Directors of each of
17 the agencies that, under subsection (c), have respon-
18 sibilities under the Program, and any other individ-
19 uals who are practitioners in the trauma field as
20 designated by the Director of the National Institutes
21 of Health.

22 “(h) DEFINITIONS.—For purposes of this section:

23 “(1) The term ‘designated trauma center’ has
24 the meaning given such term in section 1231(1).

1 “(2) The term ‘Director’ means the Director of
2 the National Institutes of Health.

3 “(3) The term ‘trauma’ means any serious in-
4 jury that could result in loss of life or in significant
5 disability and that would meet pre-hospital triage
6 criteria for transport to a designated trauma cen-
7 ter.”.

8 (b) CONFORMING AMENDMENT.—Section 402 of the
9 Public Health Service Act, as amended by section 208(c)
10 of this Act, is amended by adding at the end the following
11 new subsection:

12 “(k) The Director of NIH shall carry out the pro-
13 gram established in part E of title XII (relating to inter-
14 agency research on trauma).”.

15 **TITLE IV—NATIONAL CANCER** 16 **INSTITUTE**

17 **SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-** 18 **TIES REGARDING BREAST CANCER.**

19 Subpart 1 of part C of title IV of the Public Health
20 Service Act (42 U.S.C. 285 et seq.) is amended by adding
21 at the end the following new section:

22 “BREAST AND GYNECOLOGICAL CANCERS

23 “SEC. 417. (a) EXPANSION AND COORDINATION OF
24 ACTIVITIES.—The Director of the Institute, in consulta-
25 tion with the National Cancer Advisory Board, shall ex-
26 pand, intensify, and coordinate the activities of the Insti-

1 tute with respect to research on breast cancer, ovarian
2 cancer, and other cancers of the reproductive system of
3 women.

4 “(b) COORDINATION WITH OTHER INSTITUTES.—
5 The Director of the Institute shall coordinate the activities
6 of the Director under subsection (a) with similar activities
7 conducted by other national research institutes and agen-
8 cies of the National Institutes of Health to the extent that
9 such Institutes and agencies have responsibilities that are
10 related to breast cancer and other cancers of the reproduc-
11 tive system of women.

12 “(c) PROGRAMS FOR BREAST CANCER.—

13 “(1) IN GENERAL.—In carrying out subsection
14 (a), the Director of the Institute shall conduct or
15 support research to expand the understanding of the
16 cause of, and to find a cure for, breast cancer. Ac-
17 tivities under such subsection shall provide for an
18 expansion and intensification of the conduct and
19 support of—

20 “(A) basic research concerning the etiology
21 and causes of breast cancer;

22 “(B) clinical research and related activities
23 concerning the causes, prevention, detection and
24 treatment of breast cancer;

1 “(C) control programs with respect to
2 breast cancer in accordance with section 412;

3 “(D) information and education programs
4 with respect to breast cancer in accordance with
5 section 413; and

6 “(E) research and demonstration centers
7 with respect to breast cancer in accordance with
8 section 414, including the development and op-
9 eration of centers for breast cancer research to
10 bring together basic and clinical, biomedical and
11 behavioral scientists to conduct basic, clinical,
12 epidemiological, psychosocial, prevention and
13 treatment research and related activities on
14 breast cancer.

15 Not less than six centers shall be operated under
16 subparagraph (E). Activities of such centers should
17 include supporting new and innovative research and
18 training programs for new researchers. Such centers
19 shall give priority to expediting the transfer of re-
20 search advances to clinical applications.

21 “(2) IMPLEMENTATION OF PLAN FOR PRO-
22 GRAMS.—

23 “(A) The Director of the Institute shall en-
24 sure that the research programs described in
25 paragraph (1) are implemented in accordance

1 with a plan for the programs. Such plan shall
2 include comments and recommendations that
3 the Director of the Institute considers appro-
4 priate, with due consideration provided to the
5 professional judgment needs of the Institute as
6 expressed in the annual budget estimate pre-
7 pared in accordance with section 413(9). The
8 Director of the Institute, in consultation with
9 the National Cancer Advisory Board, shall peri-
10 odically review and revise such plan.

11 “(B) Not later than May 1, 1993, the Di-
12 rector of the Institute shall submit a copy of
13 the plan to the President’s Cancer Panel, the
14 Secretary and the Director of NIH.

15 “(C) The Director of the Institute shall
16 submit any revisions of the plan to the Presi-
17 dent’s Cancer Panel, the Secretary, and the Di-
18 rector of NIH.

19 “(D) The Secretary shall provide a copy of
20 the plan submitted under subparagraph (A),
21 and any revisions submitted under subpara-
22 graph (C), to the Committee on Energy and
23 Commerce of the House of Representatives and
24 the Committee on Labor and Human Resources
25 of the Senate.

1 “(d) OTHER CANCERS.—In carrying out subsection
2 (a), the Director of the Institute shall conduct or support
3 research on ovarian cancer and other cancers of the repro-
4 ductive system of women. Activities under such subsection
5 shall provide for the conduct and support of—

6 “(1) basic research concerning the etiology and
7 causes of ovarian cancer and other cancers of the re-
8 productive system of women;

9 “(2) clinical research and related activities into
10 the causes, prevention, detection and treatment of
11 ovarian cancer and other cancers of the reproductive
12 system of women;

13 “(3) control programs with respect to ovarian
14 cancer and other cancers of the reproductive system
15 of women in accordance with section 412;

16 “(4) information and education programs with
17 respect to ovarian cancer and other cancers of the
18 reproductive system of women in accordance with
19 section 413; and

20 “(5) research and demonstration centers with
21 respect to ovarian cancer and cancers of the repro-
22 ductive system in accordance with section 414.

23 “(e) REPORT.—The Director of the Institute shall
24 prepare, for inclusion in the biennial report submitted
25 under section 407, a report that describes the activities

1 of the National Cancer Institute under the research pro-
2 grams referred to in subsection (a), that shall include—

3 “(1) a description of the research plan with re-
4 spect to breast cancer prepared under subsection (c);

5 “(2) an assessment of the development, revi-
6 sion, and implementation of such plan;

7 “(3) a description and evaluation of the
8 progress made, during the period for which such re-
9 port is prepared, in the research programs on breast
10 cancer and cancers of the reproductive system of
11 women;

12 “(4) a summary and analysis of expenditures
13 made, during the period for which such report is
14 made, for activities with respect to breast cancer and
15 cancers of the reproductive system of women con-
16 ducted and supported by the National Institutes of
17 Health; and

18 “(5) such comments and recommendations as
19 the Director considers appropriate.”.

20 **SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVI-**
21 **TIES REGARDING PROSTATE CANCER.**

22 Subpart 1 of part C of title IV of the Public Health
23 Service Act, as amended by section 401 of this Act, is
24 amended by adding at the end the following new section:

1 “PROSTATE CANCER

2 “SEC. 417A. (a) EXPANSION AND COORDINATION OF
3 ACTIVITIES.—The Director of the Institute, in consulta-
4 tion with the National Cancer Advisory Board, shall ex-
5 pand, intensify, and coordinate the activities of the Insti-
6 tute with respect to research on prostate cancer.

7 “(b) COORDINATION WITH OTHER INSTITUTES.—
8 The Director of the Institute shall coordinate the activities
9 of the Director under subsection (a) with similar activities
10 conducted by other national research institutes and agen-
11 cies of the National Institutes of Health to the extent that
12 such Institutes and agencies have responsibilities that are
13 related to prostate cancer.

14 “(c) PROGRAMS.—

15 “(1) IN GENERAL.—In carrying out subsection
16 (a), the Director of the Institute shall conduct or
17 support research to expand the understanding of the
18 cause of, and to find a cure for, prostate cancer. Ac-
19 tivities under such subsection shall provide for an
20 expansion and intensification of the conduct and
21 support of—

22 “(A) basic research concerning the etiology
23 and causes of prostate cancer;

1 “(B) clinical research and related activities
2 concerning the causes, prevention, detection and
3 treatment of prostate cancer;

4 “(C) prevention and control and early de-
5 tection programs with respect to prostate can-
6 cer in accordance with section 412, particularly
7 as it relates to intensifying research on the role
8 of prostate specific antigen for the screening
9 and early detection of prostate cancer;

10 “(D) an Inter-Institute Task Force, under
11 the direction of the Director of the Institute, to
12 provide coordination between relevant National
13 Institutes of Health components of research ef-
14 forts on prostate cancer;

15 “(E) control programs with respect to
16 prostate cancer in accordance with section 412;

17 “(F) information and education programs
18 with respect to prostate cancer in accordance
19 with section 413; and

20 “(G) research and demonstration centers
21 with respect to prostate cancer in accordance
22 with section 414, including the development and
23 operation of centers for prostate cancer re-
24 search to bring together basic and clinical, bio-
25 medical and behavioral scientists to conduct

1 basic, clinical, epidemiological, psychosocial,
2 prevention and treatment research and related
3 activities on prostate cancer.

4 Not less than six centers shall be operated under
5 subparagraph (G). Activities of such centers should
6 include supporting new and innovative research and
7 training programs for new researchers. Such centers
8 shall give priority to expediting the transfer of re-
9 search advances to clinical applications.

10 “(2) IMPLEMENTATION OF PLAN FOR PRO-
11 GRAMS.—

12 “(A) The Director of the Institute shall en-
13 sure that the research programs described in
14 paragraph (1) are implemented in accordance
15 with a plan for the programs. Such plan shall
16 include comments and recommendations that
17 the Director of the Institute considers appro-
18 priate, with due consideration provided to the
19 professional judgment needs of the Institute as
20 expressed in the annual budget estimate pre-
21 pared in accordance with section 413(9). The
22 Director of the Institute, in consultation with
23 the National Cancer Advisory Board, shall peri-
24 odically review and revise such plan.

1 “(B) Not later than May 1, 1993, the Di-
2 rector of the Institute shall submit a copy of
3 the plan to the President’s Cancer Panel, the
4 Secretary and the Director of NIH.

5 “(C) The Director of the Institute shall
6 submit any revisions of the plan to the Presi-
7 dent’s Cancer Panel, the Secretary, and the Di-
8 rector of NIH.

9 “(D) The Secretary shall provide a copy of
10 the plan submitted under subparagraph (A),
11 and any revisions submitted under subpara-
12 graph (C), to the Committee on Energy and
13 Commerce of the House of Representatives and
14 the Committee on Labor and Human Resources
15 of the Senate.”.

16 **SEC. 403. AUTHORIZATION OF APPROPRIATIONS.**

17 (a) IN GENERAL.—Subpart 1 of part C of title IV
18 of the Public Health Service Act, as amended by section
19 402 of this Act, is amended by adding at the end the fol-
20 lowing new section:

21 “AUTHORIZATION OF APPROPRIATIONS

22 “SEC. 417B. (a) ACTIVITIES GENERALLY.—For the
23 purpose of carrying out this subpart, there are authorized
24 to be appropriated \$2,200,000,000 for fiscal year 1994,
25 and such sums as may be necessary for each of the fiscal
26 years 1995 and 1996.

1 “(b) BREAST CANCER AND GYNECOLOGICAL CAN-
2 CERS.—

3 “(1) BREAST CANCER.—

4 “(A) For the purpose of carrying out sub-
5 paragraph (A) of section 417(c)(1), there are
6 authorized to be appropriated \$225,000,000 for
7 fiscal year 1994, and such sums as may be nec-
8 essary for each of the fiscal years 1995 and
9 1996. Such authorizations of appropriations are
10 in addition to the authorizations of appropria-
11 tions established in subsection (a) with respect
12 to such purpose.

13 “(B) For the purpose of carrying out sub-
14 paragraphs (B) through (E) of section
15 417(c)(1), there are authorized to be appro-
16 priated \$100,000,000 for fiscal year 1994, and
17 such sums as may be necessary for each of the
18 fiscal years 1995 and 1996. Such authoriza-
19 tions of appropriations are in addition to the
20 authorizations of appropriations established in
21 subsection (a) with respect to such purpose.

22 “(2) OTHER CANCERS.—For the purpose of
23 carrying out subsection (d) of section 417, there are
24 authorized to be appropriated \$75,000,000 for fiscal
25 year 1994, and such sums as are necessary for each

1 of the fiscal years 1995 and 1996. Such authoriza-
2 tions of appropriations are in addition to the author-
3 izations of appropriations established in subsection
4 (a) with respect to such purpose.

5 “(c) PROSTATE CANCER.—For the purpose of carry-
6 ing out section 417A, there are authorized to be appro-
7 priated \$72,000,000 for fiscal year 1994, and such sums
8 as may be necessary for each of the fiscal years 1995 and
9 1996. Such authorizations of appropriations are in addi-
10 tion to the authorizations of appropriations established in
11 subsection (a) with respect to such purpose.

12 “(d) ALLOCATION REGARDING CANCER CONTROL.—
13 Of the amounts appropriated for the National Cancer In-
14 stitute for a fiscal year, the Director of the Institute shall
15 make available not less than 10 percent for carrying out
16 the cancer control activities authorized in section 412 and
17 for which budget estimates are made under section
18 413(b)(9) for the fiscal year.”.

19 (b) SPECIAL RULE REGARDING FUNDS FOR SECTION
20 412 FOR FISCAL YEAR 1994.—Notwithstanding section
21 417B(d) of the Public Health Service Act, as added by
22 subsection (a) of this section, the amount made available
23 under such section for fiscal year 1994 for carrying out
24 section 412 of such Act shall be an amount not less than
25 an amount equal to 75 percent of the amount specified

1 for activities under such section 412 in the budget esti-
2 mate made under section 413(b)(9) of such Act for such
3 fiscal year.

4 (c) CONFORMING AMENDMENTS.—

5 (1) IN GENERAL.—Section 408 of the Public
6 Health Service Act (42 U.S.C. 284c) is amended—

7 (A) by striking subsection (a);

8 (B) by redesignating subsection (b) as sub-
9 section (a);

10 (C) by redesignating paragraph (5) of sub-
11 section (a) (as so redesignated) as subsection
12 (b); and

13 (D) by amending the heading for the sec-
14 tion to read as follows:

15 “CERTAIN USES OF FUNDS”.

16 (2) CROSS-REFERENCE.—Section 464F of the
17 Public Health Service Act (42 U.S.C. 285m–6) is
18 amended by striking “section 408(b)(1)” and insert-
19 ing “section 408(a)(1)”.

20 **TITLE V—NATIONAL HEART,**
21 **LUNG, AND BLOOD INSTITUTE**

22 **SEC. 501. EDUCATION AND TRAINING.**

23 Section 421(b) of the Public Health Service Act (42
24 U.S.C. 285b–3(b)) is amended—

25 (1) in paragraph (3), by striking “and” after
26 the semicolon at the end;

1 (2) in paragraph (4), by striking the period at
2 the end and inserting “; and”; and

3 (3) by inserting after paragraph (4) the follow-
4 ing new paragraph:

5 “(5) shall, in consultation with the advisory
6 council for the Institute, conduct appropriate intra-
7 mural training and education programs, including
8 continuing education and laboratory and clinical re-
9 search training programs.”.

10 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CAR-**
11 **DIOVASCULAR DISEASES.**

12 Section 422(a)(1) of the Public Health Service Act
13 (42 U.S.C. 285b-4(a)(1)) is amended—

14 (1) in subparagraph (B), by striking “and” at
15 the end;

16 (2) in subparagraph (C), by striking the period
17 and inserting “; and”; and

18 (3) by adding at the end thereof the following
19 new subparagraph:

20 “(D) three centers for basic and clinical re-
21 search into, training in, and demonstration of, ad-
22 vanced diagnostic, prevention, and treatment (in-
23 cluding genetic studies, intrauterine environment
24 studies, postnatal studies, heart arrhythmias, and

1 acquired heart disease and preventive cardiology) for
2 cardiovascular diseases in children.”.

3 **SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS.**

4 Subpart 2 of part C of title IV of the Public Health
5 Service Act (42 U.S.C. 285b et seq.) is amended by adding
6 at the end the following new section:

7 “NATIONAL CENTER ON SLEEP DISORDERS

8 “SEC. 424. (a) Not later than 1 year after the date
9 of the enactment of the National Institutes of Health Re-
10 vitalization Act of 1993, the Director of the Institute shall
11 establish the National Center on Sleep Disorders (in this
12 section referred to as the ‘Center’). The Center shall head-
13 ed by a director, who shall be appointed by the Director
14 of the Institute.

15 “(b) The general purpose of the Center is the conduct
16 and support of research, training, health information dis-
17 semination, and other activities with respect to sleep dis-
18 orders.”.

19 **SEC. 504. AUTHORIZATION OF APPROPRIATIONS.**

20 Subpart 2 of part C of title IV of the Public Health
21 Service Act, as amended by section 503 of this Act, is
22 amended by adding at the end the following section:

23 “AUTHORIZATION OF APPROPRIATIONS

24 “SEC. 425. (a) For the purpose of carrying out this
25 subpart, there are authorized to be appropriated
26 \$1,500,000,000 for fiscal year 1994, and such sums as

1 may be necessary for each of the fiscal years 1995 and
2 1996.

3 “(b) Of the amounts appropriated under paragraph
4 (1) for a fiscal year, the Director of the Institute shall
5 make available not less than 10 percent for carrying out
6 prevention and control activities authorized in section
7 419.”.

8 **TITLE VI—NATIONAL INSTITUTE**
9 **ON DIABETES AND DIGESTIVE**
10 **AND KIDNEY DISEASES**

11 **SEC. 601. PROVISIONS REGARDING NUTRITIONAL DIS-**
12 **ORDERS.**

13 Subpart 3 of part C of title IV of the Public Health
14 Service Act (42 U.S.C. 285c et seq.) is amended by adding
15 at the end the following new section:

16 “NUTRITIONAL DISORDERS PROGRAM

17 “SEC. 434. (a) The Director of the Institute shall es-
18 tablish a program of conducting and supporting research,
19 training, health information dissemination, and other
20 activities with respect to nutritional disorders, including
21 obesity.

22 “(b) In carrying out the program established under
23 subsection (a), the Director of the Institute shall conduct
24 and support each of the activities described in such sub-
25 section. The Director of NIH shall ensure that, as appro-
26 priate, the other national research institutes and agencies

1 of the National Institutes of Health have responsibilities
2 regarding such activities.

3 “(c) In carrying out the program established under
4 subsection (a), the Director of the Institute shall carry out
5 activities to facilitate and enhance knowledge and under-
6 standing of nutritional disorders, including obesity, on the
7 part of health professionals, patients, and the public
8 through the effective dissemination of information.”.

9 (b) DEVELOPMENT AND EXPANSION OF RESEARCH
10 AND TRAINING CENTERS.—Section 431 of the Public
11 Health Service Act (42 U.S.C. 285c–5) is amended—

12 (1) by redesignating subsection (d) as sub-
13 section (e); and

14 (2) by inserting after subsection (c) the follow-
15 ing new subsection:

16 “(d)(1) The Director of the Institute shall, subject
17 to the extent of amounts made available in appropriations
18 Acts, provide for the development or substantial expansion
19 of centers for research and training regarding nutritional
20 disorders, including obesity.

21 “(2) The Director of the Institute shall carry out
22 paragraph (1) in collaboration with the Director of the
23 National Cancer Institute and with the Directors of such
24 other agencies of the National Institutes of Health as the
25 Director of NIH determines to be appropriate.

1 “(3) Each center developed or expanded under para-
2 graph (1) shall—

3 “(A) utilize the facilities of a single institution,
4 or be formed from a consortium of cooperating insti-
5 tutions, meeting such research and training quali-
6 fications as may be prescribed by the Director;

7 “(B) conduct basic and clinical research into
8 the cause, diagnosis, early detection, prevention, con-
9 trol and treatment of nutritional disorders, including
10 obesity and the impact of nutrition and diet on child
11 development;

12 “(C) conduct training programs for physicians
13 and allied health professionals in current methods of
14 diagnosis and treatment of such diseases and com-
15 plications, and in research in such disorders; and

16 “(D) conduct information programs for physi-
17 cians and allied health professionals who provide pri-
18 mary care for patients with such disorders or com-
19 plications.”.

1 **TITLE VII—NATIONAL INSTI-**
2 **TUTE ON ARTHRITIS AND**
3 **MUSCULOSKELETAL AND**
4 **SKIN DISEASES**

5 **SEC. 701. JUVENILE ARTHRITIS.**

6 (a) PURPOSE.—Section 435 of the Public Health
7 Service Act (42 U.S.C. 285d) is amended by striking “and
8 other programs” and all that follows and inserting the fol-
9 lowing: “and other programs with respect to arthritis and
10 musculoskeletal and skin diseases (including sports-related
11 disorders), with particular attention to the effect of these
12 diseases on children.”.

13 (b) PROGRAMS.—Section 436 (42 U.S.C. 285d–1) is
14 amended—

15 (1) in subsection (a), by inserting after the sec-
16 ond sentence, the following: “The plan shall place
17 particular emphasis upon expanding research into
18 better understanding the causes and the develop-
19 ment of effective treatments for arthritis affecting
20 children.”; and

21 (2) in subsection (b)—

22 (A) by striking “and” at the end of para-
23 graph (3);

24 (B) by striking the period at the end of
25 paragraph (4) and inserting “; and”; and

1 (C) by adding at the end thereof the fol-
2 lowing new paragraph:

3 “(5) research into the causes of arthritis affect-
4 ing children and the development, trial, and evalua-
5 tion of techniques, drugs and devices used in the di-
6 agnosis, treatment (including medical rehabilitation),
7 and prevention of arthritis in children.”.

8 (c) CENTERS.—Section 441 of the Public Health
9 Service Act (42 U.S.C. 286d–6) is amended by adding at
10 the end thereof the following new subsection:

11 “(f) Not later than October 1, 1994, the Director
12 shall establish a multipurpose arthritis and musculo-
13 skeletal disease center for the purpose of expanding the
14 level of research into the cause, diagnosis, early detection,
15 prevention, control, and treatment of, and rehabilitation
16 of children with arthritis and musculoskeletal diseases.”.

17 (d) ADVISORY BOARD.—

18 (1) TITLE.—Section 442(a) of the Public
19 Health Service Act (42 U.S.C. 285d–7(a)) is amend-
20 ed by inserting after “Arthritis” the the first place
21 such term appears the following: “and Musculo-
22 skeletal and Skin Diseases”.

23 (2) COMPOSITION.—Section 442(b) of the Pub-
24 lic Health Service Act (42 U.S.C. 285d–7(b)) is

1 amended—Section 442(b) of the Public Health Serv-
2 ice Act (42 U.S.C. 285d-7(b)) is amended—

3 (A) in the matter preceding paragraph (1),
4 by striking “eighteen” and inserting “twenty”;
5 and

6 (B) in paragraph (1)(B)—

7 (i) by striking “six” and inserting
8 “eight”; and

9 (ii) by striking “including” and all
10 that follows and inserting the following:
11 “including one member who is a person
12 who has such a disease, one person who is
13 the parent of an adult with such a disease,
14 and two members who are parents of chil-
15 dren with arthritis.”.

16 (3) ANNUAL REPORT.—Section 442(j) of the
17 Public Health Service Act (42 U.S.C. 285d-7(j)) is
18 amended—

19 (1) by striking “and” at the end of paragraph
20 (3);

21 (2) by striking the period at the end of para-
22 graph (4) and inserting “; and”; and

23 (3) by adding at the end the following para-
24 graph:

1 “(5) contains recommendations for expanding
 2 the Institute’s funding of research directly applicable
 3 to the cause, diagnosis, early detection, prevention,
 4 control, and treatment of, and rehabilitation of chil-
 5 dren with arthritis and musculoskeletal diseases.”.

6 **TITLE VIII—NATIONAL** 7 **INSTITUTE ON AGING**

8 **SEC. 801. ALZHEIMER’S DISEASE REGISTRY.**

9 (a) IN GENERAL.—Section 12 of Public Law 99–158
 10 (99 Stat. 885) is—

11 (1) transferred to subpart 5 of part C of title
 12 IV of the Public Health Service Act (42 U.S.C. 285e
 13 et seq.);

14 (2) redesignated as section 445G; and

15 (3) inserted after section 445F of such Act.

16 (b) TECHNICAL AND CONFORMING AMENDMENTS.—
 17 Section 445G of the Public Health Service Act, as trans-
 18 ferred and inserted by subsection (a) of this section, is
 19 amended—

20 (1) by striking the section heading and all that
 21 follows through “may make a grant” in subsection
 22 (a) and inserting the following:

23 “ALZHEIMER’S DISEASE REGISTRY

24 “SEC. 445G. (a) IN GENERAL.—The Director of the
 25 Institute may make a grant”; and

26 (2) by striking subsection (c).

1 **SEC. 802. AGING PROCESSES REGARDING WOMEN.**

2 Subpart 5 of part C of title IV of the Public Health
3 Service Act, as amended by section 801 of this Act, is
4 amended by adding at the end the following new section:

5 “AGING PROCESSES REGARDING WOMEN

6 “SEC. 445H. The Director of the Institute, in addi-
7 tion to other special functions specified in section 444 and
8 in cooperation with the Directors of the other national re-
9 search institutes and agencies of the National Institutes
10 of Health, shall conduct research into the aging processes
11 of women, with particular emphasis given to the effects
12 of menopause and the physiological and behavioral
13 changes occurring during the transition from pre- to post-
14 menopause, and into the diagnosis, disorders, and com-
15 plications related to aging and loss of ovarian hormones
16 in women.”.

17 **SEC. 803. AUTHORIZATION OF APPROPRIATIONS.**

18 Subpart 5 of part C of title IV of the Public Health
19 Service Act, as amended by section 802 of this Act, is
20 amended by adding at the end the following new section:

21 “AUTHORIZATION OF APPROPRIATIONS

22 “SEC. 445I. For the purpose of carrying out this sub-
23 part, there are authorized to be appropriated
24 \$500,000,000 for fiscal year 1994, and such sums as may
25 be necessary for each of the fiscal years 1995 and 1996.”.

1 **SEC. 804. CONFORMING AMENDMENT.**

2 Section 445C of the Public Health Service Act (42
3 U.S.C. 285e–5(b)) is amended—

4 (1) in subsection (b)(1), in the first sentence,
5 by inserting after “Council” the following: “on Alz-
6 heimer’s Disease (hereafter in this section referred
7 to as the ‘Council’)”; and

8 (2) by adding at the end the following new sub-
9 section:

10 “(d) For purposes of this section, the term ‘Council
11 on Alzheimer’s Disease’ means the council established in
12 section 911(a) of Public Law 99–660.”.

13 **TITLE IX—NATIONAL INSTITUTE**
14 **OF ALLERGY AND INFEC-**
15 **TIOUS DISEASES**

16 **SEC. 901. TROPICAL DISEASES.**

17 Section 446 of the Public Health Service Act (42
18 U.S.C. 285f) is amended by inserting before the period
19 the following: “, including tropical diseases”.

20 **SEC. 902. CHRONIC FATIGUE SYNDROME.**

21 (a) RESEARCH CENTERS.—Subpart 6 of part C of
22 title IV of the Public Health Service Act (42 U.S.C. 285f)
23 is amended by adding at the end the following new section:

1 “RESEARCH CENTERS REGARDING CHRONIC FATIGUE
2 SYNDROME

3 “SEC. 447. (a) The Director of the Institute, after
4 consultation with the advisory council for the Institute,
5 may make grants to, or enter into contracts with, public
6 or nonprofit private entities for the development and oper-
7 ation of centers to conduct basic and clinical research on
8 chronic fatigue syndrome.

9 “(b) Each center assisted under this section shall use
10 the facilities of a single institution, or be formed from a
11 consortium of cooperating institutions, meeting such re-
12 quirements as may be prescribed by the Director of the
13 Institute.”.

(b) EXTRAMURAL STUDY SECTION.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall establish an extramural study section for chronic fatigue syndrome research.

(c) REPRESENTATIVES.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research com-

1 munity are appointed to appropriate National Institutes
2 of Health advisory committees and boards.

3 **TITLE X—NATIONAL INSTITUTE**
4 **OF CHILD HEALTH AND**
5 **HUMAN DEVELOPMENT**

6 **Subtitle A—Research Centers With**
7 **Respect to Contraception and**
8 **Research Centers With Respect**
9 **to Infertility**

10 **SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CEN-**
11 **TERS.**

12 Subpart 7 of part C of title IV of the Public Health
13 Service Act, as amended by section 3 of Public Law 101–
14 613, is amended by adding at the end the following new
15 section:

16 “RESEARCH CENTERS WITH RESPECT TO
17 CONTRACEPTION AND INFERTILITY

18 “SEC. 452A. (a) The Director of the Institute, after
19 consultation with the advisory council for the Institute,
20 shall make grants to, or enter into contracts with, public
21 or nonprofit private entities for the development and oper-
22 ation of centers to conduct activities for the purpose of
23 improving methods of contraception and centers to con-
24 duct activities for the purpose of improving methods of
25 diagnosis and treatment of infertility.

1 “(b) In carrying out subsection (a), the Director of
2 the Institute shall, subject to the extent of amounts made
3 available in appropriations Acts, provide for the establish-
4 ment of three centers with respect to contraception and
5 for two centers with respect to infertility.

6 “(c)(1) Each center assisted under this section shall,
7 in carrying out the purpose of the center involved—

8 “(A) conduct clinical and other applied re-
9 search, including—

10 “(i) for centers with respect to contracep-
11 tion, clinical trials of new or improved drugs
12 and devices for use by males and females (in-
13 cluding barrier methods); and

14 “(ii) for centers with respect to infertility,
15 clinical trials of new or improved drugs and de-
16 vices for the diagnosis and treatment of infertil-
17 ity in males and females;

18 “(B) develop protocols for training physicians,
19 scientists, nurses, and other health and allied health
20 professionals;

21 “(C) conduct training programs for such indi-
22 viduals;

23 “(D) develop model continuing education pro-
24 grams for such professionals; and

1 “(E) disseminate information to such profes-
2 sionals and the public.

3 “(2) A center may use funds provided under sub-
4 section (a) to provide stipends for health and allied health
5 professionals enrolled in programs described in subpara-
6 graph (C) of paragraph (1), and to provide fees to individ-
7 uals serving as subjects in clinical trials conducted under
8 such paragraph.

9 “(d) The Director of the Institute shall, as appro-
10 prium, provide for the coordination of information among
11 the centers assisted under this section.

12 “(e) Each center assisted under subsection (a) shall
13 use the facilities of a single institution, or be formed from
14 a consortium of cooperating institutions, meeting such re-
15 quirements as may be prescribed by the Director of the
16 Institute.

17 “(f) Support of a center under subsection (a) may
18 be for a period not exceeding 5 years. Such period may
19 be extended for one or more additional periods not exceed-
20 ing 5 years if the operations of such center have been re-
21 viewed by an appropriate technical and scientific peer re-
22 view group established by the Director and if such group
23 has recommended to the Director that such period should
24 be extended.

1 “(g) For the purpose of carrying out this section,
 2 there are authorized to be appropriated \$30,000,000 for
 3 fiscal year 1994, and such sums as may be necessary for
 4 each of the fiscal years 1995 and 1996.”.

5 **SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH**
 6 **WITH RESPECT TO CONTRACEPTION AND IN-**
 7 **FERTILITY.**

8 Part G of title IV of the Public Health Service Act,
 9 as redesignated by section 141(a)(2) of this Act, is amend-
 10 ed by inserting after section 487A the following section:

11 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
 12 RESPECT TO CONTRACEPTION AND INFERTILITY

13 “SEC. 487B. (a) The Secretary, in consultation with
 14 the Director of the National Institute of Child Health and
 15 Human Development, shall establish a program of enter-
 16 ing into agreements with qualified health professionals (in-
 17 cluding graduate students) under which such health pro-
 18 fessionals agree to conduct research with respect to con-
 19 traception, or with respect to infertility, in consideration
 20 of the Federal Government agreeing to repay, for each
 21 year of such service, not more than \$20,000 of the prin-
 22 cipal and interest of the educational loans of such health
 23 professionals.

24 “(b) The provisions of sections 338B, 338C, and
 25 338E shall apply to the program established in subsection
 26 (a) to the same extent and in the same manner as such

1 provisions apply to the National Health Service Corps
 2 Loan Repayment Program established in subpart III of
 3 part D of title III.

4 “(c) Amounts appropriated for carrying out this sec-
 5 tion shall remain available until the expiration of the sec-
 6 ond fiscal year beginning after the fiscal year for which
 7 the amounts were appropriated.”.

8 **Subtitle B—Program Regarding** 9 **Obstetrics and Gynecology**

10 **SEC. 1011. ESTABLISHMENT OF PROGRAM.**

11 Subpart 7 of part C of title IV of the Public Health
 12 Service Act, as amended by section 1001 of this Act, is
 13 amended by adding at the end the following new section:

14 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

15 “SEC. 452B. The Director of the Institute shall es-
 16 tablish and maintain within the Institute an intramural
 17 laboratory and clinical research program in obstetrics and
 18 gynecology.”.

19 **Subtitle C—Child Health Research** 20 **Centers**

21 **SEC. 1021. ESTABLISHMENT OF CENTERS.**

22 Subpart 7 of part C of title IV of the Public Health
 23 Service Act, as amended by section 1011 of this Act, is
 24 amended by adding at the end the following new section:

1 “CHILD HEALTH RESEARCH CENTERS

2 “SEC. 452C. The Director of the Institute shall de-
3 velop and support centers for conducting research with re-
4 spect to child health. Such centers shall give priority to
5 the expeditious transfer of advances from basic science to
6 clinical applications and improving the care of infants and
7 children.”.

8 **Subtitle D—Study Regarding**
9 **Adolescent Health**

10 **SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.**

11 Subpart 7 of part C of title IV of the Public Health
12 Service Act, as amended by section 1021 of this Act, is
13 amended by adding at the end the following new section:

14 “PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT
15 HEALTH

16 “SEC. 452D. (a) IN GENERAL.—The Director of the
17 Institute shall conduct a study for the purpose of provid-
18 ing information on the general health and well-being of
19 adolescents in the United States, including, with respect
20 to such adolescents, information on—

21 “(1) the behaviors that promote health and the
22 behaviors that are detrimental to health; and

23 “(2) the influence on health of factors particu-
24 lar to the communities in which the adolescents
25 reside.

26 “(b) DESIGN OF STUDY.—

1 “(1) IN GENERAL.—The study required in sub-
2 section (a) shall be a longitudinal study in which a
3 substantial number of adolescents participate as sub-
4 jects. With respect to the purpose described in such
5 subsection, the study shall monitor the subjects
6 throughout the period of the study to determine the
7 health status of the subjects and any change in such
8 status over time.

9 “(2) POPULATION-SPECIFIC ANALYSES.—The
10 study required in subsection (a) shall be conducted
11 with respect to the population of adolescents who are
12 female, the population of adolescents who are male,
13 various socioeconomic populations of adolescents,
14 and various racial and ethnic populations of adoles-
15 cents. The study shall be designed and conducted in
16 a manner sufficient to provide for a valid analysis of
17 whether there are significant differences among such
18 populations in health status and whether and to
19 what extent any such differences are due to factors
20 particular to the populations involved.

21 “(c) COORDINATION WITH WOMEN’S HEALTH INI-
22 TIATIVE.—With respect to the national study of women
23 being conducted by the Secretary and known as the Wom-
24 en’s Health Initiative, the Secretary shall ensure that such
25 study is coordinated with the component of the study re-

1 quired in subsection (a) that concerns adolescent females,
 2 including coordination in the design of the 2 studies.

3 “(d) ALLOCATION OF FUNDS FOR STUDY.—Of the
 4 amounts appropriated for each of the fiscal years 1994
 5 through 1996 for the National Institute of Child Health
 6 and Human Development, the Secretary of Health and
 7 Human Services, acting through the Director of such In-
 8 stitute, shall reserve \$3,000,000 to conduct the study re-
 9 quired in subsection (a). The amounts so reserved shall
 10 remain available until expended.”.

11 **TITLE XI—NATIONAL EYE** 12 **INSTITUTE**

13 **SEC. 1101. CLINICAL RESEARCH ON DIABETES EYE CARE.**

14 (a) IN GENERAL.—Subpart 9 of part C of title IV
 15 of the Public Health Service Act (42 U.S.C. 285i) is
 16 amended by adding at the end the following new section:

17 “CLINICAL RESEARCH ON EYE CARE AND DIABETES

18 “SEC. 456. (a) PROGRAM OF GRANTS.—The Director
 19 of the Institute, in consultation with the advisory council
 20 for the Institute, may award not more than three grants
 21 for the establishment and support of centers for clinical
 22 research on eye care for individuals with diabetes.

23 “(b) AUTHORIZED EXPENDITURES.—The purposes
 24 for which a grant under subsection (a) may be expended
 25 include equipment for the research described in such sub-

1 section and the construction and modernization of facili-
2 ties for such research.”.

3 (b) CONFORMING AMENDMENT.—Section 455 of the
4 Public Health Service Act (42 U.S.C. 285i) is amended
5 in the second sentence by striking “The Director” and in-
6 serting “Subject to section 456, the Director”.

7 **TITLE XII—NATIONAL INSTI-**
8 **TUTE OF NEUROLOGICAL DIS-**
9 **ORDERS AND STROKE**

10 **SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.**

11 Subpart 10 of part C of title IV of the Public Health
12 Service Act (42 U.S.C. 285j et seq.) is amended by adding
13 at the end the following new section:

14 “RESEARCH ON MULTIPLE SCLEROSIS

15 “SEC. 460. The Director of the Institute shall con-
16 duct and support research on multiple sclerosis, especially
17 research on effects of genetics and hormonal changes on
18 the progress of the disease.”.

19 **TITLE XIII—NATIONAL INSTI-**
20 **TUTE OF ENVIRONMENTAL**
21 **HEALTH SCIENCES**

22 **SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TEST-**
23 **ING PROGRAM.**

24 (a) IN GENERAL.—Subpart 12 of part C of title IV
25 of the Public Health Service Act (42 U.S.C. 285l) is
26 amended by adding at the end the following new section:

1 “APPLIED TOXICOLOGICAL RESEARCH AND TESTING
2 PROGRAM

3 “SEC. 463A. (a) There is established within the Insti-
4 tute a program for conducting applied research and test-
5 ing regarding toxicology, which program shall be known
6 as the Applied Toxicological Research and Testing Pro-
7 gram.

8 “(b) In carrying out the program established under
9 subsection (a), the Director of the Institute shall, with re-
10 spect to toxicology, carry out activities—

11 “(1) to expand knowledge of the health effects
12 of environmental agents;

13 “(2) to broaden the spectrum of toxicology in-
14 formation that is obtained on selected chemicals;

15 “(3) to develop and validate assays and proto-
16 cols, including alternative methods that can reduce
17 or eliminate the use of animals in acute or chronic
18 safety testing;

19 “(4) to establish criteria for the validation and
20 regulatory acceptance of alternative testing and to
21 recommend a process through which scientifically
22 validated alternative methods can be accepted for
23 regulatory use;

1 “(5) to communicate the results of research to
 2 government agencies, to medical, scientific, and reg-
 3 ulatory communities, and to the public; and

4 “(6) to integrate related activities of the De-
 5 partment of Health and Human Services.”.

6 (b) TECHNICAL AMENDMENT.—Section 463 of the
 7 Public Health Service Act (42 U.S.C. 285l) is amended
 8 by inserting after “Sciences” the following: “(hereafter in
 9 this subpart referred to as the ‘Institute’)”.

10 **TITLE XIV—NATIONAL LIBRARY** 11 **OF MEDICINE**

12 **Subtitle A—General Provisions**

13 **SEC. 1401. ADDITIONAL AUTHORITIES.**

14 (a) IN GENERAL.—Section 465(b) of the Public
 15 Health Service Act (42 U.S.C. 286(b)) is amended—

16 (1) by striking “and” after the semicolon at the
 17 end of paragraph (5);

18 (2) by redesignating paragraph (6) as para-
 19 graph (8); and

20 (3) by inserting after paragraph (5) the follow-
 21 ing new paragraphs:

22 “(6) publicize the availability from the Library
 23 of the products and services described in any of
 24 paragraphs (1) through (5);

1 “(7) promote the use of computers and tele-
2 communications by health professionals (including
3 health professionals in rural areas) for the purpose
4 of improving access to biomedical information for
5 health care delivery and medical research; and”.

6 (b) LIMITATION REGARDING GRANTS.—Section
7 474(b)(2) of the Public Health Service Act (42 U.S.C.
8 286b–S(b)(2)) is amended by striking “\$750,000” and in-
9 serting “\$1,000,000”.

10 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

11 (1) REPEAL OF CERTAIN AUTHORITY.—Section
12 215 of the Department of Health and Human Serv-
13 ices Appropriations Act, 1988, as contained in sec-
14 tion 101(h) of Public Law 100–202 (101 Stat.
15 1329–275), is repealed.

16 (2) APPLICABILITY OF CERTAIN NEW AUTHOR-
17 ITY.—With respect to the authority established for
18 the National Library of Medicine in section
19 465(b)(6) of the Public Health Service Act, as added
20 by subsection (a) of this section, such authority shall
21 be effective as if the authority had been established
22 on December 22, 1987.

23 **SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.**

24 (a) ESTABLISHMENT OF SINGLE AUTHORIZATION.—
25 Subpart 1 of part D of title IV of the Public Health Serv-

1 ice Act (42 U.S.C. 286 et seq.) is amended by adding at
2 the end the following section:

3 “AUTHORIZATION OF APPROPRIATIONS

4 “SEC. 468. (a) For the purpose of carrying out this
5 part, there are authorized to be appropriated
6 \$150,000,000 for fiscal year 1994, and such sums as may
7 be necessary for each of the fiscal years 1995 and 1996.

8 “(b) Amounts appropriated under subsection (a) and
9 made available for grants or contracts under any of sec-
10 tions 472 through 476 shall remain available until the end
11 of the fiscal year following the fiscal year for which the
12 amounts were appropriated.”.

13 (b) CONFORMING AMENDMENTS.—Part D of title IV
14 of the Public Health Service Act (42 U.S.C. 286 et seq.)
15 is amended by striking section 469 and section 478(c).

16 **Subtitle B—Financial Assistance**

17 **SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR** 18 **DEVELOPMENT OF EDUCATION TECH-** 19 **NOLOGIES.**

20 Section 473 of the Public Health Service Act (42
21 U.S.C. 286b–4) is amended by adding at the end the fol-
22 lowing new subsection:

23 “(c)(1) The Secretary shall make grants to public or
24 nonprofit private institutions for the purpose of carrying
25 out projects of research on, and development and dem-
26 onstration of, new education technologies.

1 “(2) The purposes for which a grant under paragraph
2 (1) may be made include projects concerning—

3 “(A) computer-assisted teaching and testing of
4 clinical competence at health professions and re-
5 search institutions;

6 “(B) the effective transfer of new information
7 from research laboratories to appropriate clinical ap-
8 plications;

9 “(C) the expansion of the laboratory and clini-
10 cal uses of computer-stored research databases; and

11 “(D) the testing of new technologies for train-
12 ing health care professionals.

13 “(3) The Secretary may not make a grant under
14 paragraph (1) unless the applicant for the grant agrees
15 to make the projects available with respect to—

16 “(A) assisting in the training of health profes-
17 sions students; and

18 “(B) enhancing and improving the capabilities
19 of health professionals regarding research and teach-
20 ing.”.

1 **Subtitle C—National Information**
2 **Center on Health Services Re-**
3 **search and Health Care Tech-**
4 **nology**

5 **SEC. 1421. ESTABLISHMENT OF CENTER.**

6 Part D of title IV of the Public Health Service Act
7 (42 U.S.C. 286 et seq.) is amended by adding at the end
8 the following new subpart:

9 “Subpart 4—National Information Center on Health
10 Services Research and Health Care Technology

11 “NATIONAL INFORMATION CENTER

12 “SEC. 478A. (a) There is established within the Li-
13 brary an entity to be known as the National Information
14 Center on Health Services Research and Health Care
15 Technology (in this section referred to as the ‘Center’).

16 “(b) The purpose of the Center is the collection, stor-
17 age, analysis, retrieval, and dissemination of information
18 on health services research, clinical practice guidelines,
19 and on health care technology, including the assessment
20 of such technology. Such purpose includes developing and
21 maintaining data bases and developing and implementing
22 methods of carrying out such purpose.

23 “(c) The Director of the Center shall ensure that in-
24 formation under subsection (b) concerning clinical practice
25 guidelines is collected and maintained electronically and

1 in a convenient format. Such Director shall develop and
2 publish criteria for the inclusion of practice guidelines and
3 technology assessments in the information center
4 database.

5 “(d) The Secretary, acting through the Center, shall
6 coordinate the activities carried out under this section
7 through the Center with related activities of the Adminis-
8 trator for Health Care Policy and Research.”.

9 **SEC. 1422. CONFORMING PROVISIONS.**

10 (a) IN GENERAL.—Section 903 of the Public Health
11 Service Act, as amended by section 3 of Public Law 102–
12 410 (106 Stat. 2094), is amended to read as follows:

13 “(e) REQUIRED INTERAGENCY AGREEMENT.—The
14 Administrator and the Director of the National Library
15 of Medicine shall enter into an agreement providing for
16 the implementation of section 478A.”.

17 (b) RULE OF CONSTRUCTION.—The amendments
18 made by section 3 of Public Law 102–410 (106 Stat.
19 2094), by section 1421 of this Act, and by subsection (a)
20 of this section may not be construed as terminating the
21 information center on health care technologies and health
22 care technology assessment established under section 904
23 of the Public Health Service Act, as in effect on the day
24 before the date of the enactment of Public Law 102–410.
25 Such center shall be considered to be the center estab-

1 lished in section 478A of the Public Health Service Act,
2 as added by section 1421 of this Act, and shall be subject
3 to the provisions of such section 478A.

4 **TITLE XV—OTHER AGENCIES OF**
5 **NATIONAL INSTITUTES OF**
6 **HEALTH**

7 **Subtitle A—Division of Research**
8 **Resources**

9 **SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL**
10 **CENTER FOR RESEARCH RESOURCES.**

11 Title IV of the Public Health Service Act (42 U.S.C.
12 281 et seq.) is amended—

13 (1) in section 401(b)(2)(B), by amending such
14 subparagraph to read as follows:

15 “(B) The National Center for Research Re-
16 sources.”; and

17 (2) in part E—

18 (A) in the heading for subpart 1, by strik-
19 ing “Division of” and inserting “National Cen-
20 ter for”;

21 (B) in section 479, by striking “the Divi-
22 sion of Research Resources” and inserting the
23 following: “the National Center for Research
24 Resources (hereafter in this subpart referred to
25 as the ‘Center’)”;

1 (C) in sections 480 and 481, by striking
2 “the Division of Research Resources” each
3 place such term appears and inserting “the
4 Center”; and

5 (D) in sections 480 and 481, as amended
6 by subparagraph (C), by striking “the Division”
7 each place such term appears and inserting
8 “the Center”.

9 **SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FA-**
10 **CILITIES.**

11 Subpart 1 of part E of title IV of the Public Health
12 Service Act (42 U.S.C. 287 et seq.) is amended by adding
13 at the end the following new section:

14 “BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES
15 “SEC. 481A. (a) MODERNIZATION AND CONSTRUC-
16 TION OF FACILITIES.—

17 “(1) IN GENERAL.—The Director of NIH, act-
18 ing through the Director of the Center, may make
19 grants to public and nonprofit private entities to ex-
20 pand, remodel, renovate, or alter existing research
21 facilities or construct new research facilities, subject
22 to the provisions of this section.

23 “(2) CONSTRUCTION AND COST OF CONSTRUC-
24 TION.—For purposes of this section, the terms
25 ‘construction’ and ‘cost of construction’ include the
26 construction of new buildings and the expansion,

1 renovation, remodeling, and alteration of existing
2 buildings, including architects' fees, but do not in-
3 clude the cost of acquisition of land or off-site im-
4 provements.

5 “(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS
6 FOR MERIT-BASED REVIEW OF PROPOSALS.—

7 “(1) IN GENERAL; APPROVAL AS PRECONDITION
8 TO GRANTS.—

9 “(A) There is established within the Center
10 a Scientific and Technical Review Board on
11 Biomedical and Behavioral Research Facilities
12 (hereafter referred to in this section as the
13 ‘Board’).

14 “(B) The Director of the Center may ap-
15 prove an application for a grant under
16 subsection (a) only if the Board has under
17 paragraph (2) recommended the application for
18 approval.

19 “(2) DUTIES.—

20 “(A) The Board shall provide advice to the
21 Director of the Center and the advisory council
22 established under section 480 (hereafter in this
23 section referred to as the ‘Advisory Council’) on
24 carrying out this section.

1 “(B) In carrying out subparagraph (A),
2 the Board shall make a determination of the
3 merit of each application submitted for a grant
4 under subsection (a), after consideration of the
5 requirements established in subsection (c), and
6 shall report the results of the determination to
7 the Director of the Center and the Advisory
8 Council. Such determinations shall be con-
9 ducted in a manner consistent with procedures
10 established under section 492.

11 “(C) In carrying out subparagraph (A),
12 the Board shall, in the case of applications rec-
13 ommended for approval, make recommendations
14 to the Director and the Advisory Council on the
15 amount that should be provided in the grant.

16 “(D) In carrying out subparagraph (A),
17 the Board shall prepare an annual report for
18 the Director of the Center and the Advisory
19 Council describing the activities of the Board in
20 the fiscal year for which the report is made.
21 Each such report shall be available to the pub-
22 lic, and shall—

23 “(i) summarize and analyze expendi-
24 tures made under this section;

1 “(ii) provide a summary of the types,
2 numbers, and amounts of applications that
3 were recommended for grants under sub-
4 section (a) but that were not approved by
5 the Director of the Center; and

6 “(iii) contain the recommendations of
7 the Board for any changes in the adminis-
8 tration of this section.

9 “(3) MEMBERSHIP.—

10 “(A) Subject to subparagraph (B), the
11 Board shall be composed of such appointed and
12 ex officio members as the Director of the Cen-
13 ter may determine.

14 “(B) Not more than 3 individuals who are
15 officers or employees of the Federal Govern-
16 ment may serve as members of the Board.

17 “(C) Of the members of the Board—

18 “(i) 12 shall be appointed by the Di-
19 rector of the Center (without regard to the
20 civil service laws); and

21 “(ii) 1 shall be an official of the Na-
22 tional Science Foundation designated by
23 the National Science Board.

24 “(4) CERTAIN REQUIREMENTS REGARDING
25 MEMBERSHIP.—In selecting individuals for member-

1 ship on the Board, the Director of the Center shall
2 ensure that the members are individuals who, by the
3 virtue of their training or experience, are eminently
4 qualified to perform peer review functions. In select-
5 ing such individuals for such membership, the Direc-
6 tor of the Center shall ensure that the members of
7 the Board collectively—

8 “(A) are experienced in the planning, con-
9 struction, financing, and administration of enti-
10 ties that conduct biomedical or behavioral re-
11 search sciences;

12 “(B) are knowledgeable in making deter-
13 minations of the need of entities for biomedical
14 or behavioral research facilities, including such
15 facilities for the dentistry, nursing, pharmacy,
16 and allied health professions;

17 “(C) are knowledgeable in evaluating the
18 relative priorities for applications for grants
19 under subsection (a) in view of the overall re-
20 search needs of the United States; and

21 “(D) are experienced with emerging cen-
22 ters of excellence, as described in subsection
23 (c)(3).

24 “(5) CERTAIN AUTHORITIES.—

1 “(A) In carrying out paragraph (2), the
2 Board may establish subcommittees, convene
3 workshops and conferences, and collect data as
4 the Board considers appropriate.

5 “(B) In carrying out paragraph (2), the
6 Board may establish subcommittees within the
7 Board. Such subcommittees may hold meetings
8 as determined necessary to enable the sub-
9 committee to carry out its duties.

10 “(6) TERMS.—

11 “(A) Except as provided in subparagraph
12 (B), each appointed member of the Board shall
13 hold office for a term of 4 years. Any member
14 appointed to fill a vacancy occurring prior to
15 the expiration of the term for which such mem-
16 ber’s predecessor was appointed shall be ap-
17 pointed for the remainder of the term of the
18 predecessor.

19 “(B) Of the initial members appointed to
20 the Board (as specified by the Director of the
21 Center when making the appointments)—

22 “(i) 3 shall hold office for a term of
23 3 years;

24 “(ii) 3 shall hold office for a term of
25 2 years; and

1 “(iii) 3 shall hold office for a term of
2 1 year.

3 “(C) No member is eligible for reappoint-
4 ment to the Board until 1 year has elapsed
5 after the end of the most recent term of the
6 member.

7 “(7) COMPENSATION.—Members of the Board
8 who are not officers or employees of the United
9 States shall receive for each day the members are
10 engaged in the performance of the functions of the
11 Board compensation at the same rate received by
12 members of other national advisory councils estab-
13 lished under this title.

14 “(c) REQUIREMENTS FOR GRANTS.—

15 “(1) IN GENERAL.—The Director of the Center
16 may make a grant under subsection (a) only if the
17 applicant for the grant meets the following condi-
18 tions:

19 “(A) The applicant is determined by such
20 Director to be competent to engage in the type
21 of research for which the proposed facility is to
22 be constructed.

23 “(B) The applicant provides assurances
24 satisfactory to the Director that—

1 “(i) for not less than 20 years after
2 completion of the construction, the facility
3 will be used for the purposes of research
4 for which it is to be constructed;

5 “(ii) sufficient funds will be available
6 to meet the non-Federal share of the cost
7 of constructing the facility;

8 “(iii) sufficient funds will be available,
9 when construction is completed, for the ef-
10 fective use of the facility for the research
11 for which it is being constructed; and

12 “(iv) the proposed construction will
13 expand the applicant’s capacity for re-
14 search, or is necessary to improve or main-
15 tain the quality of the applicant’s research.

16 “(C) The applicant meets reasonable quali-
17 fications established by the Director with re-
18 spect to—

19 “(i) the relative scientific and tech-
20 nical merit of the applications, and the rel-
21 ative effectiveness of the proposed facili-
22 ties, in expanding the capacity for bio-
23 medical or behavioral research and in im-
24 proving the quality of such research;

1 “(ii) the quality of the research or
2 training, or both, to be carried out in the
3 facilities involved;

4 “(iii) the need of the applicant for
5 such facilities in order to maintain or ex-
6 pand the applicant’s research and training
7 mission;

8 “(iv) the congruence of the research
9 activities to be carried out within the facil-
10 ity with the research and investigator man-
11 power needs of the United States; and

12 “(v) the age and condition of existing
13 research facilities and equipment.

14 “(D) The applicant has demonstrated a
15 commitment to enhancing and expanding the
16 research productivity of the applicant.

17 “(2) CONSIDERATION OF CERTAIN FACTORS.—
18 In making grants under subsection (a), the Director
19 of the Center may, in addition to the requirements
20 established in paragraph (1), consider the following
21 factors:

22 “(A) To what extent the applicant has the
23 capacity to broaden the scope of research and
24 research training programs of the applicant by
25 promoting—

1 “(i) interdisciplinary research;

2 “(ii) research on emerging tech-
3 nologies, including those involving novel
4 analytical techniques or computational
5 methods; or

6 “(iii) other novel research mechanisms
7 or programs.

8 “(B) To what extent the applicant has
9 broadened the scope of research and research
10 training programs of qualified institutions by
11 promoting genomic research with an emphasis
12 on interdisciplinary research, including research
13 related to pediatric investigations.

14 “(3) INSTITUTIONS OF EMERGING EXCEL-
15 LENCE.—Of the amounts appropriated under sub-
16 section (i) for a fiscal year, the Director of the Cen-
17 ter shall make available 25 percent for grants under
18 subsection (a) to applicants that, in addition to
19 meeting the requirements established in paragraph
20 (1), have demonstrated emerging excellence in bio-
21 medical or behavioral research, as follows:

22 “(A) The applicant has a plan for research
23 or training advancement and possesses the abil-
24 ity to carry out the plan.

1 “(B) The applicant carries out research
2 and research training programs that have a
3 special relevance to a problem, concern, or
4 unmet health need of the United States.

5 “(C) The applicant has been productive in
6 research or research development and training.

7 “(D) The applicant—

8 “(i) has been designated as a center
9 of excellence under section 739;

10 “(ii) is located in a geographic area a
11 significant percentage of whose population
12 has a health-status deficit, and the appli-
13 cant provides health services to such popu-
14 lation; or

15 “(iii) is located in a geographic area
16 in which a deficit in health care tech-
17 nology, services, or research resources may
18 adversely affect health status of the popu-
19 lation of the area in the future, and the
20 applicant is carrying out activities with re-
21 spect to protecting the health status of
22 such population.

23 “(d) REQUIREMENT OF APPLICATION.—The Director
24 of the Center may make a grant under subsection (a) only
25 if an application for the grant is submitted to the Director

1 and the application is in such form, is made in such man-
2 ner, and contains such agreements, assurances, and infor-
3 mation as the Director determines to be necessary to carry
4 out this section.

5 “(e) AMOUNT OF GRANT; PAYMENTS.—

6 “(1) AMOUNT.—The amount of any grant
7 awarded under subsection (a) shall be determined by
8 the Director of the Center, except that such amount
9 shall not exceed—

10 “(A) 50 percent of the necessary cost of
11 the construction of a proposed facility as deter-
12 mined by the Director; or

13 “(B) in the case of a multipurpose facility,
14 40 percent of that part of the necessary cost of
15 construction that the Director determines to be
16 proportionate to the contemplated use of the fa-
17 cility.

18 “(2) RESERVATION OF AMOUNTS.—On approval
19 of any application for a grant under subsection (a),
20 the Director of the Center shall reserve, from any
21 appropriation available therefore, the amount of
22 such grant, and shall pay such amount, in advance
23 or by way of reimbursement, and in such install-
24 ments consistent with the construction progress, as
25 the Director may determine appropriate. The res-

1 ervation of the Director of any amount by the Direc-
2 tor under this paragraph may be amended by the
3 Director, either on the approval of an amendment of
4 the application or on the revision of the estimated
5 cost of construction of the facility.

6 “(3) EXCLUSION OF CERTAIN COSTS.—In deter-
7 mining the amount of any grant under this sub-
8 section (a), there shall be excluded from the cost of
9 construction an amount equal to the sum of—

10 “(A) the amount of any other Federal
11 grant that the applicant has obtained, or is as-
12 sured of obtaining, with respect to construction
13 that is to be financed in part by a grant author-
14 ized under this section; and

15 “(B) the amount of any non-Federal funds
16 required to be expended as a condition of such
17 other Federal grant.

18 “(4) WAIVER OF LIMITATIONS.—The limita-
19 tions imposed by paragraph (1) may be waived at
20 the discretion of the Director for applicants meeting
21 the conditions described in paragraphs (1) and (2)
22 of subsection (c).

23 “(f) RECAPTURE OF PAYMENTS.—If, not later than
24 20 years after the completion of construction for which
25 a grant has been awarded under subsection (a)—

1 “(1) the applicant or other owner of the facility
2 shall cease to be a public or nonprofit private entity;
3 or

4 “(2) the facility shall cease to be used for the
5 research purposes for which it was constructed (un-
6 less the Director determines, in accordance with reg-
7 ulations, that there is good cause for releasing the
8 applicant or other owner from obligation to do so);
9 the United States shall be entitled to recover from the ap-
10 plicant or other owner of the facility the amount bearing
11 the same ratio to the current value (as determined by an
12 agreement between the parties or by action brought in the
13 United States District Court for the district in which such
14 facility is situated) of the facility as the amount of the
15 Federal participation bore to the cost of the construction
16 of such facility.

17 “(g) NONINTERFERENCE WITH ADMINISTRATION OF
18 ENTITIES.—Except as otherwise specifically provided in
19 this section, nothing contained in this part shall be con-
20 strued as authorizing any department, agency, officer, or
21 employee of the United States to exercise any direction,
22 supervision, or control over, or impose any requirement
23 or condition with respect to the administration of any en-
24 tity funded under this part.

1 “(h) GUIDELINES.—Not later than 6 months after
2 the date of the enactment of this section, the Director of
3 the Center, after consultation with the Advisory Council,
4 shall issue guidelines with respect to grants under sub-
5 section (a).

6 “(i) AUTHORIZATION OF APPROPRIATIONS.—For the
7 purpose of carrying out this section, there are authorized
8 to be appropriated \$150,000,000 for fiscal year 1994, and
9 such sums as may be necessary for each of the fiscal years
10 1995 and 1996.”.

11 SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRI-
12 MATE RESEARCH CENTER.

Subpart 1 of part E of title IV of the Public Health
Service Act, as amended by section 1502 of this Act, is
amended by adding at the end the following new section:

16 “CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH
17 ON PRIMATES

18 “SEC. 481B. (a) With respect to activities carried out
19 by the National Center for Research Resources to support
20 regional centers for research on primates, the Director of
21 NIH shall, for each of the fiscal years 1994 through 1996,
22 reserve from the amounts appropriated under section
23 481A(i) \$7,000,000 for the purpose of making awards of
24 grants and contracts to public or nonprofit private entities
25 to construct, renovate, or otherwise improve such regional
26 centers. The reservation of such amounts for any fiscal

1 year is subject to the availability of qualified applicants
2 for such awards.

3 “(b) The Director of NIH may not make a grant or
4 enter into a contract under subsection (a) unless the appli-
5 cant for such assistance agrees, with respect to the costs
6 to be incurred by the applicant in carrying out the purpose
7 described in such subsection, to make available (directly
8 or through donations from public or private entities) non-
9 Federal contributions in cash toward such costs in an
10 amount equal to not less than \$1 for each \$4 of Federal
11 funds provided in such assistance.”.

12 **Subtitle B—National Center for** 13 **Nursing Research**

14 **SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR** 15 **NURSING RESEARCH AS NATIONAL INSTI-** 16 **TUTE OF NURSING RESEARCH.**

17 (a) IN GENERAL.—Subpart 3 of part E of title IV
18 of the Public Health Service Act (42 U.S.C. 287c et seq.)
19 is amended—

20 (1) in section 483—

21 (A) in the heading for the section, by strik-
22 ing “CENTER” and inserting “INSTITUTE”; and

23 (B) by striking “The general purpose” and
24 all that follows through “is” and inserting the
25 following: “The general purpose of the National

1 Institute of Nursing Research (hereafter in this
2 subpart referred to as the ‘Institute’) is”;

3 (2) in section 484, by striking “Center” each
4 place such term appears and inserting “Institute”;

5 (3) in section 485—

6 (A) in subsection (a), in each of para-
7 graphs (1) through (3), by striking “Center”
8 each place such term appears and inserting
9 “Institute”;

10 (B) in subsection (b)—

11 (i) in paragraph (2)(A), by striking
12 “Center” and inserting “Institute”; and

13 (ii) in paragraph (3)(A), in the first
14 sentence, by striking “Center” and insert-
15 ing “Institute”; and

16 (C) in subsections (d) through (g), by
17 striking “Center” each place such term appears
18 and inserting “Institute”; and

19 (4) in section 485A (as redesignated by section
20 141(a)(1) of this Act), by striking “Center” each
21 place such term appears and inserting “Institute”.

22 (b) CONFORMING AMENDMENTS.—

23 (1) ORGANIZATION OF NATIONAL INSTITUTE OF
24 HEALTH.—Section 401(b) of the Public Health
25 Service Act (42 U.S.C. 281(b)) is amended—

1 (A) in paragraph (1), by adding at the end
2 the following new subparagraph:

3 “(Q) The National Institute of Nursing
4 Research.”; and

5 (B) in paragraph (2), by striking subpara-
6 graph (D).

7 (2) TRANSFER OF STATUTORY PROVISIONS.—
8 Sections 483 through 485A of the Public Health
9 Service Act, as amended by subsection (a) of this
10 section—

11 (A) are transferred to part C of title IV of
12 such Act;

13 (B) are redesignated as sections 464V
14 through 464Y of such part; and

15 (C) are inserted, in the appropriate se-
16 quence, at the end of such part.

17 (3) HEADING FOR NEW SUBPART.—Title IV of
18 the Public Health Service Act, as amended by the
19 preceding provisions of this section, is amended—

20 (A) in part C, by inserting before section
21 464V the following new heading:

22 “Subpart 17—National Institute of Nursing Research”;

23 and

24 (B) by striking the heading for subpart 3
25 of part E.

1 (4) CROSS-REFERENCES.—Title IV of the Pub-
2 lic Health Service Act, as amended by the preceding
3 provisions of this section, is amended in subpart 17
4 of part C—

5 (A) in section 464W, by striking “section
6 483” and inserting “section 464V”;

7 (B) in section 464X(g), by striking “sec-
8 tion 486” and inserting “section 464Y”; and

9 (C) in section 464Y, in the last sentence,
10 by striking “section 485(g)” and inserting “sec-
11 tion 464X(g)”.

12 **SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services, acting through the Director of the Na-
15 tional Institute of Nursing Research, shall enter into a
16 contract with a public or nonprofit private entity to con-
17 duct a study for the purpose of determining whether and
18 to what extent there is a need for an increase in the num-
19 ber of nurses in hospitals and nursing homes in order to
20 promote the quality of patient care and reduce the inci-
21 dence among nurses of work-related injuries and stress.

22 (b) NATIONAL ACADEMY OF SCIENCES.—The Sec-
23 retary shall request the National Academy of Sciences to
24 enter into the contract under subsection (a) to conduct
25 the study described in such subsection. If such Institute

1 declines to conduct the study, the Secretary shall carry
2 out such subsection through another public or nonprofit
3 private entity.

4 (c) DEFINITIONS.—For purposes of this section:

5 (1) The term “nurse” means a registered nurse,
6 a licensed practical nurse, a licensed vocational
7 nurse, and a nurse assistant.

8 (2) The term “Secretary” means the Secretary
9 of Health and Human Services.

10 (d) REPORT.—The Secretary shall ensure that, not
11 later than October 1, 1994, the study required in sub-
12 section (a) is completed and a report describing the find-
13 ings made as a result of the study is submitted to the
14 Committee on Energy and Commerce of the House of
15 Representatives, and to the Committee on Labor and
16 Human Resources of the Senate.

17 **Subtitle C—National Center for**
18 **Human Genome Research**

19 **SEC. 1521. PURPOSE OF CENTER.**

20 Title IV of the Public Health Service Act, as amended
21 by sections 141(a)(1) and 1611(b)(1)(B) of this Act, is
22 amended—

23 (1) in section 401(b)(2), by adding at the end
24 the following new subparagraph:

1 “(D) The National Center for Human Genome
2 Research.”; and

3 (2) in part E, by adding at the end the follow-
4 ing new subpart:

“Subpart 4—National Center for Human Genome
Research

7 “PURPOSE OF THE CENTER

8 “SEC. 485B. (a) The general purpose of the National
9 Center for Human Genome Research (hereafter in this
10 subpart referred to as the ‘Center’) is to characterize the
11 structure and function of the human genome, including
12 the mapping and sequencing of individual genes. Such
13 purpose includes—

14 “(1) planning and coordinating the research
15 goal of the genome project;

16 “(2) reviewing and funding research proposals;

17 “(3) developing training programs;

18 “(4) coordinating international genome re-
19 search;

20 “(5) communicating advances in genome science
21 to the public; and

22 “(6) reviewing and funding proposals to address
23 the ethical issues associated with the genome
24 project.

1 “(b)(1) Except as provided in paragraph (2), of the
 2 amounts appropriated to carry out subsection (a) for a
 3 fiscal year, the Director of the Center shall make available
 4 not less than 5 percent for carrying out paragraph (6)
 5 of such subsection.

6 “(2) With respect to providing funds under sub-
 7 section (a)(6) for proposals to address the ethical issues
 8 associated with the genome project, paragraph (1) shall
 9 not apply for a fiscal year if the Director of the Center
 10 certifies to the Committee on Energy and Commerce of
 11 the House of Representatives, and to the Committee on
 12 Labor and Human Resources of the Senate, that the Di-
 13 rector has determined that an insufficient number of such
 14 proposals meet the applicable requirements of sections 491
 15 and 492.”.

16 **TITLE XVI—AWARDS AND** 17 **TRAINING**

18 **Subtitle A—National Research** 19 **Service Awards**

20 **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDIV-** 21 **VIDUALS FROM DISADVANTAGED BACK-** 22 **GROUND.**

23 Section 487(a) of the Public Health Service Act (42
 24 U.S.C. 288(a)(4)) is amended by adding at the end the
 25 following paragraph:

1 “(4) The Secretary shall carry out paragraph (1) in
2 a manner that will result in the recruitment of women,
3 and individuals from disadvantaged backgrounds, into
4 fields of biomedical or behavioral research and in the pro-
5 vision of research training to women and such individ-
6 uals.”.

7 **Subtitle B—Acquired Immune**
8 **Deficiency Syndrome**

9 **SEC. 1611. LOAN REPAYMENT PROGRAM.**

10 Section 487A of the Public Health Service Act (42
11 U.S.C. 288–1) is amended to read as follows:

12 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
13 RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME
14 “SEC. 487A. (a) IN GENERAL.—

15 “(1) AUTHORITY FOR PROGRAM.—Subject to
16 paragraph (2), the Secretary shall carry out a pro-
17 gram of entering into agreements with appropriately
18 qualified health professionals under which such
19 health professionals agree to conduct, as employees
20 of the National Institutes of Health, research with
21 respect to acquired immune deficiency syndrome in
22 consideration of the Federal Government agreeing to
23 repay, for each year of such service, not more than
24 \$20,000 of the principal and interest of the edu-
25 cational loans of such health professionals.

1 “(2) LIMITATION.—The Secretary may not
2 enter into an agreement with a health professional
3 pursuant to paragraph (1) unless such profes-
4 sional—

5 “(A) has a substantial amount of edu-
6 cational loans relative to income; and

7 “(B)(i) was not employed at the National
8 Institutes of Health during the 1-year period
9 preceding the date of the enactment of the
10 Health Professions Reauthorization Act of
11 1988; or

12 “(ii) agrees to serve as an employee of
13 such Institutes for purposes of paragraph (1)
14 for a period of not less than 3 years.”.

15 “(b) APPLICABILITY OF CERTAIN PROVISIONS.—
16 With respect to the National Health Service Corps Loan
17 Repayment Program established in subpart III of part D
18 of title III, the provisions of such subpart shall, except
19 as inconsistent with subsection (a) of this section, apply
20 to the program established in such subsection (a) in the
21 same manner and to the same extent as such provisions
22 apply to the National Health Service Corps Loan Repay-
23 ment Program established in such subpart.

24 “(c) FUNDING; REIMBURSABLE TRANSFERS.—

1 “(1) AUTHORIZATION OF APPROPRIATIONS.—

2 For the purpose of carrying out this section, there
3 are authorized to be appropriated such sums as may
4 be necessary for each of the fiscal years 1994
5 through 1996.

6 “(2) TRANSFERS FOR RELATED PROGRAM.—

7 The Commissioner of Food and Drugs may carry
8 out for the Food and Drug Administration a pro-
9 gram similar to the program established in sub-
10 section (a), which program shall be carried out with
11 respect to the review of applications concerning ac-
12 quired immune deficiency syndrome that are submit-
13 ted to such Commissioner. From the amounts appro-
14 priated under paragraph (1) for a fiscal year, the
15 Secretary may transfer amounts to the Commis-
16 sioner for the purpose of carrying out such program.
17 The Commissioner shall provide a reimbursement to
18 the Secretary for the amount so transferred, and the
19 reimbursement shall be available only for the pro-
20 gram established in subsection (a). Any transfer and
21 reimbursement made for purposes of this paragraph
22 for a fiscal year shall be completed by April 1 of
23 such year.”.

1 **Subtitle C—Loan Repayment for**
2 **Research Generally**

3 SEC. 1621. ESTABLISHMENT OF PROGRAM.

4 Part G of title IV of the Public Health Service Act,
5 as redesignated by section 141(a)(2) of this Act and as
6 amended by section 1002 of this Act, is amended by in-
7 serting after section 487B the following new section:

8 “LOAN REPAYMENT PROGRAM FOR RESEARCH
9 GENERALLY

10 “SEC. 487C. (a) IN GENERAL.—

“(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of such health professionals.

“ (2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

1 “(A) has a substantial amount of edu-
2 cational loans relative to income; and

3 “(B)(i) was not employed at the National
4 Institutes of Health during the 1-year period
5 preceding the date of the enactment of the
6 Health Professions Reauthorization Act of
7 1988; or

8 “(ii) agrees to serve as an employee of
9 such Institutes for purposes of paragraph (1)
10 for a period of not less than 3 years.”.

11 “(b) APPLICABILITY OF CERTAIN PROVISIONS.—
12 With respect to the National Health Service Corps Loan
13 Repayment Program established in subpart III of part D
14 of title III, the provisions of such subpart shall, except
15 as inconsistent with subsection (a) of this section, apply
16 to the program established in such subsection (a) in the
17 same manner and to the same extent as such provisions
18 apply to the National Health Service Corps Loan Repay-
19 ment Program established in such subpart.

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
21 purpose of carrying out this section other than with re-
22 spect to acquired immune deficiency syndrome, there are
23 authorized to be appropriated such sums as may be nec-
24 essary for each of the fiscal years 1994 through 1996.”.

1 **Subtitle D—Scholarship and Loan**
2 **Repayment Programs Regard-**
3 **ing Professional Skills Needed**
4 **by Certain Agencies**

5 **SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL**
6 **INSTITUTES OF HEALTH.**

7 Part G of title IV of the Public Health Service Act,
8 as redesignated by section 141(a)(2) of this Act and as
9 amended by section 1621 of this Act, is amended by in-
10 serting after section 487C the following new sections:

11 “UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING
12 PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-
13 STITUTES

14 “SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—

15 “(1) IN GENERAL.—Subject to section
16 487(a)(1)(C), the Secretary, acting through the Di-
17 rector of NIH, may carry out a program of entering
18 into contracts with individuals described in para-
19 graph (2) under which—

20 “(A) the Director of NIH agrees to provide
21 to the individuals scholarships for pursuing, as
22 undergraduates at accredited institutions of
23 higher education, academic programs appro-
24 priate for careers in professions needed by the
25 National Institutes of Health; and

1 “(B) the individuals agree to serve as em-
2 ployees of the National Institutes of Health, for
3 the period described in subsection (c), in posi-
4 tions that are needed by the National Institutes
5 of Health and for which the individuals are
6 qualified.

7 “(2) INDIVIDUALS FROM DISADVANTAGED
8 BACKGROUNDS.—The individuals referred to in
9 paragraph (1) are individuals who—

10 “(A) are enrolled or accepted for enroll-
11 ment as full-time undergraduates at accredited
12 institutions of higher education; and

13 “(B) are from disadvantaged backgrounds.

14 “(b) FACILITATION OF INTEREST OF STUDENTS IN
15 CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In
16 providing employment to individuals pursuant to contracts
17 under subsection (a)(1), the Director of NIH shall carry
18 out activities to facilitate the interest of the individuals
19 in pursuing careers as employees of the National Insti-
20 tutes of Health.

21 “(c) PERIOD OF OBLIGATED SERVICE.—

22 “(1) DURATION OF SERVICE.—For purposes of
23 subparagraph (B) of subsection (a)(1), the period of
24 service for which an individual is obligated to serve
25 as an employee of the National Institutes of Health

1 is 12 months for each academic year for which the
2 scholarship under such subsection is provided.

3 “(2) SCHEDULE FOR SERVICE.—

4 “(A) Subject to subparagraph (B), the Di-
5 rector of NIH may not provide a scholarship
6 under subsection (a) unless the individual ap-
7 plying for the scholarship agrees that—

8 “(i) the individual will serve as an em-
9 ployee of the National Institutes of Health
10 full-time for not less than 10 consecutive
11 weeks of each year during which the indi-
12 vidual is attending the educational institu-
13 tion involved and receiving such a scholar-
14 ship;

15 “(ii) the period of service as such an
16 employee that the individual is obligated to
17 provide under clause (i) is in addition to
18 the period of service as such an employee
19 that the individual is obligated to provide
20 under subsection (a)(1)(B); and

21 “(iii) not later than 60 days after ob-
22 taining the educational degree involved, the
23 individual will begin serving full-time as
24 such an employee in satisfaction of the pe-
25 riod of service that the individual is obli-

1 gated to provide under subsection
2 (a)(1)(B).

3 “(B) The Director of NIH may defer the
4 obligation of an individual to provide a period
5 of service under subsection (a)(1)(B), if the Di-
6 rector determines that such a deferral is appro-
7 priate.

8 “(3) APPLICABILITY OF CERTAIN PROVISIONS
9 RELATING TO APPOINTMENT AND COMPENSATION.—
10 For any period in which an individual provides serv-
11 ice as an employee of the National Institutes of
12 Health in satisfaction of the obligation of the indi-
13 vidual under subsection (a)(1)(B) or paragraph
14 (2)(A)(i), the individual may be appointed as such
15 an employee without regard to the provisions of title
16 5, United States Code, relating to appointment and
17 compensation.

18 “(d) PROVISIONS REGARDING SCHOLARSHIP.—

19 “(1) APPROVAL OF ACADEMIC PROGRAM.—The
20 Director of NIH may not provide a scholarship
21 under subsection (a) for an academic year unless—

22 “(A) the individual applying for the schol-
23 arship has submitted to the Director a proposed
24 academic program for the year and the Director
25 has approved the program; and

1 “(B) the individual agrees that the pro-
2 gram will not be altered without the approval of
3 the Director.

4 “(2) ACADEMIC STANDING.—The Director of
5 NIH may not provide a scholarship under subsection
6 (a) for an academic year unless the individual apply-
7 ing for the scholarship agrees to maintain an accept-
8 able level of academic standing, as determined by
9 the educational institution involved in accordance
10 with regulations issued by the Secretary.

11 “(3) LIMITATION ON AMOUNT.—The Director
12 of NIH may not provide a scholarship under sub-
13 section (a) for an academic year in an amount ex-
14 ceeding \$20,000.

15 “(4) AUTHORIZED USES.—A scholarship pro-
16 vided under subsection (a) may be expended only for
17 tuition expenses, other reasonable educational ex-
18 penses, and reasonable living expenses incurred in
19 attending the school involved.

20 “(5) CONTRACT REGARDING DIRECT PAYMENTS
21 TO INSTITUTION.—In the case of an institution of
22 higher education with respect to which a scholarship
23 under subsection (a) is provided, the Director of
24 NIH may enter into a contract with the institution
25 under which the amounts provided in the scholarship

1 for tuition and other educational expenses are paid
2 directly to the institution. Payments to the institu-
3 tion under the contract may be made without regard
4 to section 3324 of title 31, United States Code.

5 “(e) PENALTIES FOR BREACH OF SCHOLARSHIP
6 CONTRACT.—The provisions of section 338E shall apply
7 to the program established in subsection (a) to the same
8 extent and in the same manner as such provisions apply
9 to the National Health Service Corps Loan Repayment
10 Program established in section 338B.

11 “(f) REQUIREMENT OF APPLICATION.—The Director
12 of NIH may not provide a scholarship under subsection
13 (a) unless an application for the scholarship is submitted
14 to the Director and the application is in such form, is
15 made in such manner, and contains such agreements, as-
16 surances, and information as the Director determines to
17 be necessary to carry out this section.

18 “(g) AVAILABILITY OF AUTHORIZATION OF APPRO-
19 PRIATIONS.—Amounts appropriated for a fiscal year for
20 scholarships under this section shall remain available until
21 the expiration of the second fiscal year beginning after the
22 fiscal year for which the amounts were appropriated.

23 “LOAN REPAYMENT PROGRAM REGARDING CLINICAL
24 RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

25 “SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

1 “(1) IN GENERAL.—Subject to section
2 487(a)(1)(C), the Secretary, acting through the Di-
3 rector of NIH may, subject to paragraph (2), carry
4 out a program of entering into contracts with appro-
5 priately qualified health professionals who are from
6 disadvantaged backgrounds under which such health
7 professionals agree to conduct clinical research as
8 employees of the National Institutes of Health in
9 consideration of the Federal Government agreeing to
10 pay, for each year of such service, not more than
11 \$20,000 of the principal and interest of the edu-
12 cational loans of the health professionals.

13 “(2) LIMITATION.—The Director of NIH may
14 not enter into a contract with a health professional
15 pursuant to paragraph (1) unless such professional
16 has a substantial amount of education loans relative
17 to income.

18 “(3) APPLICABILITY OF CERTAIN PROVISIONS
19 REGARDING OBLIGATED SERVICE.—Except to the ex-
20 tent inconsistent with this section, the provisions of
21 sections 338C and 338E shall apply to the program
22 established in paragraph (1) to the same extent and
23 in the same manner as such provisions apply to the
24 National Health Service Corps Loan Repayment
25 Program established in section 338B.

1 “(b) AVAILABILITY OF AUTHORIZATION OF APPRO-
2 PRIATIONS.—Amounts appropriated for a fiscal year for
3 contracts under subsection (a) shall remain available until
4 the expiration of the second fiscal year beginning after the
5 fiscal year for which the amounts were appropriated.”.

6 **SEC. 1632. FUNDING.**

7 Section 487(a)(1) of the Public Health Service Act
8 (42 U.S.C. 288(a)(1)) is amended—

9 (1) in subparagraph (A), by striking “and”
10 after the semicolon at the end;

11 (2) in subparagraph (B), by striking the period
12 at the end and inserting “; and”; and

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(C) provide contracts for scholarships and loan
16 repayments in accordance with sections 487D and
17 487E, subject to providing not more than an aggre-
18 gate 50 such contracts during the fiscal years 1994
19 through 1996.”.

20 **Subtitle D—Funding**

21 **SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.**

22 Section 487(d) of the Public Health Service Act (42
23 U.S.C. 288(d)) is amended—

24 (1) in the first sentence, by amending the sen-
25 tence to read as follows: “For the purpose of carry-

1 ing out this section, there are authorized to be ap-
 2 propriated \$400,000,000 for fiscal year 1994, and
 3 such sums as may be necessary for each of the fiscal
 4 years 1995 and 1996.”; and

5 (2) in paragraph (3)—

6 (A) by striking “one-half of one percent”
 7 each place such term appears and inserting “1
 8 percent”; and

9 (B) by inserting “785,” after “784,”.

10 **TITLE XVII—NATIONAL FOUNDA-**
 11 **TION FOR BIOMEDICAL RE-**
 12 **SEARCH**

13 **SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD**
 14 **MEMBERS.**

15 Section 499 of the Public Health Service Act, as re-
 16 designated by section 121(b)(3) of this Act, is amended
 17 in subsection (c)(1)(C) by inserting after and below clause
 18 (iii) the following:

19 “Not later than March 1, 1993, the Secretary
 20 shall convene a meeting of the ex officio mem-
 21 bers of the Board for the purpose of making
 22 the appointments required in this subpara-
 23 graph.”.

1 **SEC. 1702. MISCELLANEOUS PROVISIONS.**

2 Section 499 of the Public Health Service Act, as re-
3 designated by section 121(b)(3) of this Act, is amended—

4 (1) in subsection (a)—

5 (A) in the first sentence, by inserting after
6 “Secretary” the following: “, acting through the
7 Director of NIH,”; and

8 (B) in the second sentence, by striking
9 “the purposes of” and all that follows through
10 “Transfer Act,” and inserting the following:
11 “the purposes of the Ethics in Government Act
12 of 1978 and the Stevenson-Wydler Technology
13 Innovation Act of 1980,”;

14 (2) in subsection (b)(2), by striking “Ethics”
15 and all that follows and inserting the following:
16 “Ethics in Government Act of 1978, and the Steven-
17 son-Wydler Technology Innovation Act of 1980.”;

18 (3) in subsection (c)—

19 (A) in paragraph (1)—

20 (i) in subparagraph (A), in the second
21 sentence, by inserting “, except the ex
22 officio members,” after “Foundation”;

23 (ii) in subparagraph (B), in the mat-
24 ter preceding clause (i), by striking “Coun-
25 cil” and inserting “Board”; and

1 (iii) in subparagraph (C), in the first
 2 sentence, by striking “Council” and insert-
 3 ing “Board”; and

4 (B) in paragraph (3)(A), by striking
 5 “paragraph (2)(C)” and inserting “paragraph
 6 (1)(C)”;

7 (4) in subsection (g)(8), by striking “subtitle”
 8 and inserting “part”; and
 9 (5) in subsection (i)(1), by striking “1995” and
 10 inserting “1996”.

11 **TITLE XVIII—RESEARCH WITH**
 12 **RESPECT TO ACQUIRED IM-**
 13 **MUNE DEFICIENCY SYN-**
 14 **DROME**

15 **SEC. 1801. REVISION AND EXTENSION OF VARIOUS PRO-**
 16 **GRAMS.**

17 Title XXIII of the Public Health Service Act (42
 18 U.S.C. 300cc et seq.) is amended—

19 (1) in section 2304(c)(1)—

20 (A) in the matter preceding subparagraph
 21 (A), by inserting after “Director of such Insti-
 22 tute” the following: “(and may provide advice
 23 to the Directors of other agencies of the Na-
 24 tional Institutes of Health, as appropriate)”;
 25 and

1 (B) in subparagraph (A), by inserting be-
2 fore the semicolon the following: “, including
3 recommendations on the projects of research
4 with respect to diagnosing immune deficiency
5 and with respect to predicting, diagnosing, pre-
6 venting, and treating opportunistic cancers and
7 infectious diseases”;

8 (2) in section 2311(a)(1), by inserting before
9 the semicolon the following: “, including evaluations
10 of methods of diagnosing immune deficiency and
11 evaluations of methods of predicting, diagnosing,
12 preventing, and treating opportunistic cancers and
13 infectious diseases”;

14 (3) in section 2315—

15 (A) in subsection (a)(2), by striking “inter-
16 national research” and all that follows and in-
17 serting “international research and training
18 concerning the natural history and pathogenesis
19 of the human immunodeficiency virus and the
20 development and evaluation of vaccines and
21 treatments for acquired immune deficiency syn-
22 drome and opportunistic infections.”; and

23 (B) in subsection (f), by striking “and
24 1991” and inserting “through 1996”;

25 (4) in section 2318—

1 (A) in subsection (a)(1)—

2 (i) by inserting after “The Secretary”
3 the following: “, acting through the Direc-
4 tor of the National Institutes of Health
5 and after consultation with the Adminis-
6 trator for Health Care Policy and Re-
7 search,”; and

8 (ii) by striking “syndrome” and in-
9 serting “syndrome, including treatment
10 and prevention of HIV infection and relat-
11 ed conditions among women”; and

12 (B) in subsection (e), by striking “1991.”
13 and inserting the following: “1991, and such
14 sums as may be necessary for each of the fiscal
15 years 1994 through 1996.”;

16 (5) in section 2320(b)(1)(A), by striking “syn-
17 drome” and inserting “syndrome and the natural
18 history of such infection”;

19 (6)(A) in section 2351(a)—

20 (i) by redesignating paragraphs (2)
21 through (8) as paragraphs (3) through (9); and

22 (ii) by inserting after paragraph (1) the
23 following new paragraph:

24 “(2)(A) shall develop and implement a com-
25 prehensive plan for the conduct and support of such

1 research by the agencies of the National Institutes
2 of Health, which plan shall specify the objectives to
3 be achieved, the date by which the objectives are ex-
4 pected to be achieved, and an estimate of the re-
5 sources needed to achieve the objectives by such
6 date; and

7 “(B) shall develop and implement a plan for
8 evaluating the sufficiency of the plan developed
9 under subparagraph (A) and for evaluating the ex-
10 tent to which activities of the National Institutes of
11 Health have been in accordance with the plan;” and

12 (B) in section 2301(b)(6), by inserting before
13 the semicolon the following: “, including evaluations
14 conducted under section 2351(a)(2)(B)”;

15 (7) in section 2361, by striking “For purposes”
16 and all that follows and inserting the following:
17 “For purposes of this title:

18 “(1) The term ‘infection’, with respect to the
19 etiologic agent for acquired immune deficiency syn-
20 drome, includes opportunistic cancers and infectious
21 diseases and any other conditions arising from infec-
22 tion with such etiologic agent.

23 “(2) The term ‘treatment’, with respect to the
24 etiologic agent for acquired immune deficiency syn-

1 drome, includes primary and secondary prophylaxis.”;

3 (8) in section 2315(f), by striking “there are
4 authorized” and all that follows and inserting “there
5 are authorized to be appropriated such sums as may
6 be necessary for each fiscal year.”;

7 (9) in section 2320(e)(1), by striking “there are
8 authorized” and all that follows and inserting “there
9 are authorized to be appropriated such sums as may
10 be necessary for each fiscal year.”; and

11 (10) in section 2341(d), by striking “there are
12 authorized” and all that follows and inserting “there
13 are authorized to be appropriated such sums as may
14 be necessary for each fiscal year.”.

15 **TITLE XIX—STUDIES**

16 **SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

17 (a) CERTAIN DRUG-RELEASE MECHANISMS.—

18 (1) The Secretary of Health and Human Services shall, subject to paragraph (2), enter into a contract with a public or nonprofit private entity to conduct a study for the purpose of determining, with respect to acquired immune deficiency syndrome, the impact of parallel-track drug-release mechanisms on public and private clinical research, and on the ac-

1 activities of the Commissioner of Food and Drugs re-
2 garding the approval of drugs.

3 (2) The Secretary of Health and Human Serv-
4 ices shall request the Institute of Medicine of the
5 National Academy of Sciences to enter into the con-
6 tract under paragraph (1) to conduct the study de-
7 scribed in such paragraph. If such Institute declines
8 to conduct the study, the Secretary shall carry out
9 paragraph (1) through another public or nonprofit
10 private entity.

11 (b) THIRD-PARTY PAYMENTS REGARDING CERTAIN
12 CLINICAL TRIALS.—The Secretary of Health and Human
13 Services, acting through the Director of the National In-
14 stitutes of Health, shall conduct a study for the purpose
15 of—

16 (1) determining the policies of third-party
17 payors regarding the payment of the costs of appro-
18 priate health services that are provided incident to
19 the participation of individuals as subjects in clinical
20 trials conducted in the development of drugs with re-
21 spect to acquired immune deficiency syndrome; and

22 (2) developing recommendations regarding such
23 policies.

24 (c) ADVISORY COMMITTEES.—The Secretary of
25 Health and Human Services, acting through the Director

1 of the National Institutes of Health, shall conduct a study
2 for the purpose of determining—

3 (1) whether the activities of the various advisory
4 committees established in the National Institutes of Health regarding acquired immune deficiency syndrome are being coordinated sufficiently;
5
6 and
7

8 (2) whether the functions of any of such advisory
9 committees should be modified in order to
10 achieve greater efficiency.

11 (d) VACCINES FOR HUMAN IMMUNODEFICIENCY
12 VIRUS.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services, acting through the National Institutes of Health, shall develop a plan for the appropriate inclusion of HIV-infected women, including
15 pregnant women, HIV-infected infants, and HIV-infected children in studies conducted by or through
16 the National Institutes of Health concerning the
17 safety and efficacy of HIV vaccines for the treatment and prevention of HIV infection. Such plan
18 shall ensure the full participation of other Federal
19 agencies currently conducting HIV vaccine studies
20 and require that such studies conform fully to the
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1 requirements of part 46 of title 45, Code of Federal
2 Regulations.

3 (2) REPORT.—Not later than 180 days after
4 the date of the enactment of this Act, the Secretary
5 of Health and Human Services shall prepare and
6 submit to the Committee on Energy and Commerce
7 of the House of Representatives, and the Committee
8 on Labor and Human Resources of the Senate, a re-
9 port concerning the plan developed under paragraph
10 (1).

11 (3) IMPLEMENTATION.—Not later than 12
12 months after the date of the enactment of this Act,
13 the Secretary of Health and Human Services shall
14 implement the plan developed under paragraph (1),
15 including measures for the full participation of other
16 Federal agencies currently conducting HIV vaccine
17 studies.

18 (4) For the purpose of carrying out this sub-
19 section, there are authorized to be appropriated such
20 sums as may be necessary for each of the fiscal
21 years 1994 through 1996.

22 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

23 (a) STUDY.—

24 (1) IN GENERAL.—The Secretary of Health and
25 Human Services (referred to in this section as the

1 “Secretary”), acting through the National Institute
2 on Aging, coordinating with the Agency for Health
3 Care Policy and Research and, to the degree pos-
4 sible, in consultation with the head of the National
5 Nutrition Monitoring System established under sec-
6 tion 1428 of the Food and Agriculture Act of 1977
7 (7 U.S.C. 3178), shall conduct a 3-year nutrition
8 screening and intervention activities study of the el-
9 derly.

10 (2) EFFICACY AND COST-EFFECTIVENESS OF
11 NUTRITION SCREENING AND INTERVENTION ACTIVI-
12 TIES.—In conducting the study, the Secretary shall
13 determine the efficacy and cost-effectiveness of nu-
14 trition screening and intervention activities con-
15 ducted in the elderly health and long-term care con-
16 tinuum, and of a program that would institutionalize
17 nutrition screening and intervention activities. In
18 evaluating such a program, the Secretary shall de-
19 termine—

20 (A) if health or quality of life is measur-
21 ably improved for elderly individuals who re-
22 ceive routine nutritional screening and treat-
23 ment;

24 (B) if federally subsidized home or institu-
25 tional care is reduced because of increased inde-

pendence of elderly individuals resulting from improved nutritional status;

(C) if a multidisciplinary approach to nutritional care is effective in addressing the nutritional needs of elderly individuals; and

(D) if reimbursement for nutrition screening and intervention activities is a cost-effective approach to improving the health status of elderly individuals.

(3) POPULATIONS.—The populations of elderly individuals in which the study will be conducted shall include populations of elderly individuals who are—

(A) living independently, including—

(i) individuals who receive home and community-based services or family support;

(ii) individuals who do not receive additional services and support;

(iii) individuals with low incomes; and

(iv) individuals who are minorities;

(B) hospitalized, including individuals admitted from home and from institutions; and

(C) institutionalized in residential facilities such as nursing homes and adult homes.

1 (b) MALNUTRITION STUDY.—The Secretary, acting
2 through the National Institute on Aging, shall conduct a
3 3-year study to determine the extent of malnutrition in
4 elderly individuals in hospitals and long-term care facili-
5 ties and in elderly individuals who are living independ-
6 ently.

7 (c) REPORT.—The Secretary shall submit a report to
8 the Committee on Labor and Human Resources of the
9 Senate and the Committee on Energy and Commerce of
10 the House of Representatives containing the findings re-
11 sulting from the studies described in subsections (a) and
12 (b), including a determination regarding whether a pro-
13 gram that would institutionalize nutrition screening and
14 intervention activities should be adopted, and the rationale
15 for the determination.

16 (d) ADVISORY PANEL.—

17 (1) ESTABLISHMENT.—The Secretary, acting
18 through the Director of the National Institute on
19 Aging, shall establish an advisory panel that shall
20 oversee the design, implementation, and evaluation
21 of the studies described in subsections (a) and (b).

22 (2) COMPOSITION.—The advisory panel shall in-
23 clude representatives appointed for the life of the
24 panel by the Secretary from the Health Care Fi-
25 nancing Administration, the Social Security Admin-

1 istration, the National Center for Health Statistics,
2 the Administration on Aging, the National Council
3 on the Aging, the American Dietetic Association, the
4 American Academy of Family Physicians, and such
5 other agencies or organizations as the Secretary de-
6 termines to be appropriate.

7 (3) COMPENSATION AND EXPENSES.—

8 (A) COMPENSATION.—Each member of the
9 advisory panel who is not an employee of the
10 Federal Government shall receive compensation
11 at the daily equivalent of the rate specified for
12 level V of the Executive Schedule under section
13 5316 of title 5, United States Code, for each
14 day the member is engaged in the performance
15 of duties for the advisory panel, including at-
16 tendance at meetings and conferences of the
17 panel, and travel to conduct the duties of the
18 panel.

19 (B) TRAVEL EXPENSES.—Each member of
20 the advisory panel shall receive travel expenses,
21 including per diem in lieu of subsistence, at
22 rates authorized for employees of agencies
23 under subchapter I of chapter 57 of title 5,
24 United States Code, for each day the member
25 is engaged in the performance of duties away

1 from the home or regular place of business of
2 the member.

3 (4) DETAIL OF FEDERAL EMPLOYEES.—On the
4 request of the advisory panel, the head of any Fed-
5 eral agency shall detail, without reimbursement, any
6 of the personnel of the agency to the advisory panel
7 to assist the advisory panel in carrying out its du-
8 ties. Any detail shall not interrupt or otherwise af-
9 fect the civil service status or privileges of the Fed-
10 eral employee.

11 (5) TECHNICAL ASSISTANCE.—On the request
12 of the advisory panel, the head of a Federal agency
13 shall provide such technical assistance to the advi-
14 sory panel as the advisory panel determines to be
15 necessary to carry out its duties.

16 (6) TERMINATION.—Notwithstanding section
17 15 of the Federal Advisory Committee Act (5 U.S.C.
18 App.), the advisory panel shall terminate 3 years
19 after the date of enactment of this Act.

20 **SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE**
21 **SYNDROME.**

22 The Secretary of Health and Human Services shall,
23 not later than May 1, 1993, and annually thereafter for
24 the next 3 years, prepare and submit to the Committee
25 on Energy and Commerce of the House of Representatives

1 and the Committee on Labor and Human Resources of
2 the Senate, a report that summarizes the research activi-
3 ties conducted or supported by the National Institutes of
4 Health concerning chronic fatigue syndrome. Such report
5 should include information concerning grants made, coop-
6 erative agreements or contracts entered into, intramural
7 activities, research priorities and needs, and a plan to ad-
8 dress such priorities and needs.

9 **SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL**
10 **AGENTS IN DEVELOPMENT OF DEFENSES**
11 **AGAINST BIOLOGICAL WARFARE.**

12 The Secretary of Health and Human Services, in con-
13 sultation with other appropriate executive agencies, shall
14 report to the House Energy and Commerce Committee
15 and the Senate Labor and Human Resources Committee
16 on the appropriateness and impact of the National Insti-
17 tutes of Health assuming responsibility for the conduct of
18 all Federal research, development, testing, and evaluation
19 functions relating to medical countermeasures against
20 biowarfare threat agents. In preparing the report, the Sec-
21 retary shall identify the extent to which such activities are
22 carried out by agencies other than the National Institutes
23 of Health, and assess the impact (positive and negative)
24 of the National Institutes of Health assuming responsibil-
25 ity for such activities, including the impact under the

1 Budget Enforcement Act and the Omnibus Budget Rec-
2 onciliation Act of 1990 on existing National Institutes of
3 Health research programs as well as other programs with-
4 in the category of domestic discretionary spending. The
5 Secretary shall submit the report not later than 12 months
6 after the date of the enactment of this Act.

7 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**
8 **TION AND TURNOVER.**

9 (a) STUDY OF PERSONNEL SYSTEM.—Not later than
10 1 year after the date of the enactment of this Act, the
11 Secretary of Health and Human Services, acting through
12 the Director of the National Institutes of Health, shall
13 conduct a study to review the retention, recruitment, va-
14 cancy and turnover rates of support staff, including fire-
15 fighters, law enforcement, procurement officers, techni-
16 cians, nurses and clerical employees, to ensure that the
17 National Institutes of Health is adequately supporting the
18 conduct of efficient, effective and high quality research for
19 the American public. The Director of NIH shall work in
20 conjunction with appropriate employee organizations and
21 representatives in developing such a study.

22 (b) SUBMISSION TO CONGRESS.—Not later than 1
23 year after the date of the enactment of this Act, the Sec-
24 retary of Health and Human Services shall prepare and
25 submit to the Committee on Energy and Commerce of the

1 House of Representatives, and to the Committee on Labor
2 and Human Resources of the Senate, a report containing
3 the study conducted under subsection (a) together with
4 the recommendations of the Secretary concerning the en-
5 actment of legislation to implement the results of such
6 study.

7 **SEC. 1906. PROCUREMENT.**

8 (a) IN GENERAL.—The Director of the National In-
9 stitutes of Health and the Administrator of the General
10 Services Administration shall jointly conduct a study to
11 develop a streamlined procurement system for the Na-
12 tional Institutes of Health that complies with the require-
13 ments of Federal law.

14 (b) REPORT.—Not later than March 1, 1994, the of-
15 ficials specified in subsection (a) shall complete the study
16 required in such subsection and shall submit to the Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives, and the Committee on Labor and Human Re-
19 sources of the Senate, a report describing the findings
20 made as a result of the study.

1 **TITLE XX—MISCELLANEOUS**
2 **PROVISIONS**

3 **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-**
4 **SEARCH SERVICE IN HONOR OF SILVIO O.**
5 **CONTE, AND LIMITATION ON NUMBER OF**
6 **MEMBERS.**

7 (a) IN GENERAL.—Section 228(a) of the Public
8 Health Service Act (42 U.S.C. 237(a)), as added by sec-
9 tion 304 of Public Law 101–509, is amended to read as
10 follows:

11 “(a)(1) There shall be in the Public Health Service
12 a Silvio O. Conte Senior Biomedical Research Service, not
13 to exceed 750 members.

14 “(2) The authority established in paragraph (1) re-
15 garding the number of members in the Silvio O. Conte
16 Senior Biomedical Research Service is in addition to any
17 authority established regarding the number of members
18 in the commissioned Regular Corps, in the Reserve Corps,
19 and in the Senior Executive Service. Such paragraph may
20 not be construed to require that the number of members
21 in the commissioned Regular Corps, in the Reserve Corps,
22 or in the Senior Executive Service be reduced to offset
23 the number of members serving in the Silvio O. Conte Sen-
24 ior Biomedical Research Service (hereafter in this section
25 referred to as the ‘Service’).”.

1 (b) CONFORMING AMENDMENT.—Section 228 of the
2 Public Health Service Act (42 U.S.C. 237), as added by
3 section 304 of Public Law 101–509, is amended in the
4 heading for the section by amending the heading to read
5 as follows:

6 “SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH
7 SERVICE”.

8 **SEC. 2002. TECHNICAL CORRECTIONS.**

9 (a) TITLE IV.—Title IV of the Public Health Service
10 Act (42 U.S.C. 281 et seq.) is amended—

11 (1) in section 406—

12 (A) in subsection (b)(2)(A), by striking
13 “Veterans’ Administration” each place such
14 term appears and inserting “Department of
15 Veterans Affairs”; and

16 (B) in subsection (h)(2)(A)(v), by striking
17 “Veterans’ Administration” and inserting “De-
18 partment of Veterans Affairs”;

19 (2) in section 408, in subsection (b) (as redesign-
20 nated by section 501(c)(1)(C) of this Act), by strik-
21 ing “Veterans’ Administration” and inserting “De-
22 partment of Veterans Affairs”;

23 (3) in section 421(b)(1), by inserting a comma
24 after “may”;

1 (4) in section 428(b), in the matter preceding
2 paragraph (1), by striking “the the” and inserting
3 “the”;

4 (5) in section 430(b)(2)(A)(i), by striking “Vet-
5 erans’ Administration” and inserting “Department
6 of Veterans Affairs”;

7 (6) in section 439(b), by striking “Veterans’
8 Administration” and inserting “Department of Vet-
9 erans Affairs”;

10 (7) in section 442(b)(2)(A), by striking “Veter-
11 ans’ Administration” and inserting “Department of
12 Veterans Affairs”;

13 (8) in section 464D(b)(2)(A), by striking “Vet-
14 erans’ Administration” and inserting “Department
15 of Veterans Affairs”;

16 (9) in section 464E—

17 (A) in subsection (d), in the first sentence,
18 by inserting “Coordinating” before “Commit-
19 tee”; and

20 (B) in subsection (e), by inserting “Coordi-
21 nating” before “Committee” the first place
22 such term appears;

23 (10) in section 464P(b)(6) (as added by section
24 123 of Public Law 102–321 (106 Stat. 362)), by
25 striking “Administration” and inserting “Institute”;

1 (11) in section 466(a)(1)(B), by striking “Vet-
2 erans’ Administration” and inserting “Department
3 of Veterans Affairs”;

4 (12) in section 480(b)(2)(A), by striking “Vet-
5 erans’ Administration” and inserting “Department
6 of Veterans Affairs”;

7 (13) in section 485(b)(2)(A), by striking “Vet-
8 erans’ Administration” and inserting “Department
9 of Veterans Affairs”;

10 (14) in section 487(d)(3), by striking “section
11 304(a)(3)” and inserting “section 304(a)”; and

12 (15) in section 496(a), by striking “Such ap-
13 propriations,” and inserting the following: “Appro-
14 priations to carry out the purposes of this title,”.

15 (b) TITLE XXIII.—Part A of title XXIII of the Pub-
16 lic Health Service Act (42 U.S.C. 300cc et seq.) is amend-
17 ed—

18 (1) in section 2304—

19 (A) in the heading for the section, by strik-
20 ing “**CLINICAL RESEARCH REVIEW COM-**
21 **MITTEE**” and inserting “**RESEARCH ADVI-**
22 **SORY COMMITTEE**”; and

23 (B) in subsection (a), by striking “AIDS
24 Clinical Research Review Committee” and in-
25 serting “AIDS Research Advisory Committee”;

1 (2) in section 2312(a)(2)(A), by striking “AIDS
2 Clinical Research Review Committee” and inserting
3 “AIDS Research Advisory Committee”;

4 (3) in section 2314(a)(1), in the matter preced-
5 ing subparagraph (A), by striking “Clinical Research
6 Review Committee” and inserting “AIDS Research
7 Advisory Committee”;

8 (4) in section 2317(d)(1), by striking “Clinical
9 Research Review Committee” and inserting “AIDS
10 Research Advisory Committee established under sec-
11 tion 2304”; and

12 (5) in section 2318(b)(3), by striking “Clinical
13 Research Review Committee” and inserting “AIDS
14 Research Advisory Committee”.

15 **SEC. 2003. BIENNIAL REPORT ON CARCINOGENS.**

16 Section 301(b)(4) of the Public Health Service Act
17 (42 U.S.C. 241(b)(4)) is amended by striking “an annual”
18 and inserting in lieu thereof “a biennial”.

19 **SEC. 2004. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE**
20 **FOR RESEARCH.**

21 Not later than 90 days after the date of the enact-
22 ment of this Act, the Secretary of Health and Human
23 Services, acting through the Director of the National In-
24 stitutes of Health, shall present to the Congress a master
25 plan to provide for the replacement or refurbishment of

1 less than adequate buildings, utility equipment and dis-
2 tribution systems (including the resources that provide
3 electrical and other utilities, chilled water, air handling,
4 and other services that the Secretary, acting through the
5 Director, deems necessary), roads, walkways, parking
6 areas, and grounds that underpin the laboratory and clini-
7 cal facilities of the National Institutes of Health. Such
8 plan may make recommendations for the undertaking of
9 new projects that are consistent with the objectives of this
10 section, such as encircling the National Institutes of
11 Health Federal enclave with an adequate chilled water
12 conduit.

13 **SEC. 2005. TRANSFER OF PROVISIONS OF TITLE XXVII.**

14 (a) IN GENERAL.—The Public Health Service Act
15 (42 U.S.C. 201 et seq.), as amended by section 101 of
16 Public Law 101–381 and section 304 of Public Law 101–
17 509, is amended—

18 (1) by transferring sections 2701 through 2714
19 to title II;

20 (2) by redesignating such sections as sections
21 231 through 244, respectively;

22 (3) by inserting such sections, in the appro-
23 priate sequence, after section 228;

24 (4) by inserting before section 201 the following
25 new heading:

1 “PART A—ADMINISTRATION”; and

2 (5) by inserting before section 231 (as redesignig-
3 nated by paragraph (2) of this subsection) the fol-
4 lowing new heading:

5 “Part B—Miscellaneous Provisions”.

6 (b) CONFORMING AMENDMENTS.—The Public
7 Health Service Act (42 U.S.C. 201 et seq.) is amended—

8 (1) in the heading for title II, by inserting
9 “AND MISCELLANEOUS PROVISIONS” after
10 “ADMINISTRATION”;

11 (2) in section 406(a)(2), by striking “2701”
12 and inserting “231”;

13 (3) in section 465(f), by striking “2701” and
14 inserting “231”;

15 (4) in section 480(a)(2), by striking “2701”
16 and inserting “231”;

17 (5) in section 485(a)(2), by striking “2701”
18 and inserting “231”;

19 (6) in section 497, by striking “2701” and in-
20 serting “231”;

21 (7) in section 505(a)(2), by striking “2701”
22 and inserting “231”;

23 (8) in section 926(b), by striking “2711” each
24 place such term appears and inserting “241”; and

1 (9) in title XXVII, by striking the heading for
2 such title.

3 **SEC. 2006. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

4 Section 399L(a) of the Public Health Service Act (42
5 U.S.C. 280e-4(a)), as added by Public Law 102-515 (106
6 Stat. 3376), is amended—

7 (1) in the first sentence, by striking “the Sec-
8 retary” and all that follows and inserting the follow-
9 ing: “there are authorized to be appropriated
10 \$30,000,000 for fiscal year 1994, and such sums as
11 may be necessary for each of the fiscal years 1995
12 through 1997.”; and

13 (2) in the second sentence, by striking “Out of
14 any amounts used” and inserting “Of the amounts
15 appropriated under the preceding sentence”.

16 **TITLE XXI—EFFECTIVE DATES**

17 **SEC. 2101. EFFECTIVE DATES.**

18 Subject to section 155, this Act and the amendments
19 made by this Act take effect upon the date of the enact-
20 ment of this Act.

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